A STUDY ON
CEGANA VATHAM
(Cervical spondylosis)

Dissertation Submitted To

THE TAMIL NADU Dr. M.G.R. Medical University

Chennai – 32

For the Partial fulfillment for the Award of Degree of

DOCTOR OF MEDICINE (SIDDHA)

(Branch – III, SIRAPPU MARUTHUVAM)

DEPARTMENT OF SIRAPPU MARUTHUVAM

Government Siddha Medical College

Palayamkottai – 627 002.

OCTOBER - 2018

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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled **"A STUDY ON CEGANA VATHAM** is a bonafide work done by **Dr. K. ELAKKIYA, (Reg No: 321513002) GOVERNMENT SIDDHA MEDICAL COLLEGE, PALAYAMKOTTAI** in partial fulfillment of the University rules and regulations for award of **M.D (SIDDHA), BRANCH - III SIRAPPU MARUTHUVAM** under my guidance and supervision during the academic year **2015-2018 OCTOBER.**

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Name and Signature of the Head of Department:

Name and Signature of the Principal :

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"A STUDY ON CEGANA VATHAM"** is a bonafide and genuine research work carried out by me under the guidance of **Prof. Dr. A. S. POONGODI KANTHIMATHI., M.D(s).,** HOD, PG - Department of Sirappu Maruthuvam, Govt. Siddha Medical College, Palayamkottai and the dissertation has formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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This is to certify that the dissertation topic an open clinical study to evaluate the efficacy of siddha sashtric formulation VATHATHIRKU LEGHIYAM "(INDERNAL).....PANCHARKA....THYLAM(EXTERNAL) for the treatment of .....CEGANA...VATHAM..... had been approved by the screening committee.

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CERTIFICATE OF APPROVAL

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Principal investigator	Dr.K.Elakkiya. I Year PG Dept of Sirrapu Maruthuvam Reg.No :
Supervisor &Guide	Dr.A.S.Poongodi kanthimathi. M.D (s) Professor &Head of the Department
Dissertation topic	An open clinical Study to evaluate the clinical efficacy of siddha sasthric formulation "**VATHATHIRKU LEGHIYAM**"(Internal) "**PANCHARKA THYLAM**"for the treatment of **CEGANA VATHAM.**
Document field	1. Protocol2. Date Collection Form 3. Patient Information Sheet 4. Consent form5. SAE (Pharmacovigilance)
Clinical / Non Clinical trial Protocol	Clinical trial protocol – Yes
Informed consent document	Yes
Any other document	Case sheet, Investigation document
Date of IEC approval & it's Number	GSMC/3.IEC/2016/III-21/20.07.16

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

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CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified the following plant drugs used in siddha formulation **VATHATHIRKU LEGHIYAM (INTERNAL) & PANCHARKA THYLAM (EXTERNAL)** for management of **CEGANA VATHAM(Cervical spondylosis)** taken up for post-graduation dissertation studies by **Dr.K.ELAKKIYA M.D (S)., (REG.NO:321513002)** ,PG scholar, department of sirappu maruthuvam are correctly identified and authenticated through Visual inspection / Organoleptic characters / Experience, Education & Training morphology, microscopical and taxonomical methods.

INGREDIENTS VATHATHIRKU LEGHIYAM

S.NO	DRUGS	BOTANICAL NAME	FAMILY	PART USED
1.	Poondu	Allium sativum	Liliaceae	Bulb
2.	Chathipaththiri	Myristica fragrans	Myristicaceae	Aril
3.	Sathikkai	Myristica fragrans	Myristicaceae	Seed
4.	Seeragam	Cuminum cyminum	Apiaceae	Fruit
5.	Kirambu	Syzygium aromaticum	Myrtaceae	Flower bud
6.	Elam	Elettaria Cardamomum	Zingiberaceae	Fruit
7.	Akkarakaram	Anacyclus Pyrethrum	Asteraceae	Rhizome
8.	Thipilimoolam	(Piper longum)	Piperaceae	Root
9.	Chukku	Zingiber officinale	Zingiberaceae	Rhizome
10.	Milagu	Piper nigrum	Piperaceae	Unriped fruit
11.	Thippili	Piper longum	Piperaceae	Fruit
12.	Omam	Tachyspermum ammi	Apiaceae	Fruit
13.	Parangipattai	Smilax China	Liliaceae	Root
14.	Nilapanai kizhangu	Curculigo orchioides	Hypoxidaceae	Rhizome

INGREDIENTS OF PANCHARKA THYLAM

S.NO	DRUGS	BOTANICAL NAME	FAMILY	PART USED
1.	Erukkam Samoola Sarru	Calotropis gigantea	Asclepiadaceae	Leaf,stem,Root
2.	Amukkura	Withania somnifera	Solanaceae	Root
3.	Murungai	Moringa oleifera	Moringaceae	Bark
4.	Veliparuthi	Pergularia daemia	Asclepidaceae	Leaf
5.	Charanai	Trianthema Portulacastrum	Aizoaceae	Root
6.	Athandai	Capparis zeylanica	Capparaceae	Root
7.	Notchi	Vitex negundo	Verbenaceae	Leaf
8.	Mukkirattai	Boerhaavia disffusa	Nystaginaceae	Leaf
9.	Thagarai Vithai	Cassia tora	Caesalpiniaceae	Seed
10.	Kirambu	syzygium aromaticum	Myrtaceae	Flower bud
11.	Chukku	Zingiber offcinale	Zingiberaceae	Rhizome
12.	Elakkai	Elettaria Caradamomum	Zingiberaceae	Fruit
13.	Kottam	Saussurea lappa	Asteraceae	Root
14.	Kasthuri Manjal	Curcuma aromatica	Zingiberaceae	Rhizome

Station:

Date:

Authorized Signature

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CERTIFICATE OF GUNAPADAM AUTHENTICITY

Certified the following metals & mineral drugs used in siddha formulation **VATHATHIRKU LEGHIYAM (INTERNAL) & PANCHARKA THYLAM (EXTERNAL)** for management of **CEGANA VATHAM(Cervical spondylosis)** taken up for post-graduation dissertation studies by **Dr.K.ELAKKIYA M.D (S)., (REG.NO:321513002)** PG scholar, department of sirappu maruthuvam are correctly identified and authenticated through Visual inspection / Organoleptic characters / Experience, Education & Training morphology, microscopical and taxonomical methods.

METALS & MINERAL INGREDIENTS OF SANTHUVATHA CHOORANAM

S.NO	TAMIL NAME	ENGLISH NAME	CHEMICAL NAME
1.	Indhuppu	Rock salt	Sodium cholride impura

Station: Palayamkottai.

Date: 14.06.17.

14/6/17

Authorized signature

Dr. A. KINGSLY MD (S)
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Head of the Department
PG Gunapadam
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Palayamkottai.

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IAEC APPROVAL CERTIFICATE

This is to certify that the project **Evaluation of Anti-inflammatory, Analgesic And Toxicological Profile of Vathathirku Leghiyam** has been approved by the IAEC, KMCH College of Pharmacy, Coimbatore.

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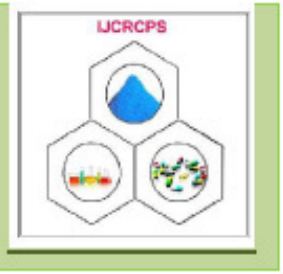

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INTRODUCTION

Man is a wonderful creature blessed by God. Imagination and laughter are milestone on the way that distinguishes man from other animals of mere living, no man was ever proud, but the good life had always been his aim.

To desire among goods the greatest good which is the most desirable, thus to be trusted to the self, to prefer among beautiful things, the grandeur beauty, thus to weigh objective things most truly, to worship that only which reflects infinite value, for this sound mind, one needs sounds body. Health stated which not only keeps the body sound but also the mind.

Today's modern industrialization imbalance the ecosystem which paves way for many disease. To uproot the disease there should be a system of medicine which goes hand in hand with nature. The Siddha system of medicine is an "Indigenous system of Medicine". The unique nature of this system is its continuation of service to humanity from time immemorial. Siddha system of medicine is ancient one, it is believed to be originated from Agasthiyar to Siddhars, from Siddhars this system of medicine gifted to mankind. The siddha system has been involved by the hard work and hearted contribution of Tamil sages turned Medical scientists called "Siddhars".

The ultimate aim of siddhars is to attain eternal bliss. For attaining eternal bliss human body is considered to be a media. This media must be protected from degeneration ageing and disease. So the siddhars followed specific type of life style and food style which was also included in this system.

The advantage and unique features of siddha system is the removal of the root cause of the disease and provide perfect remedy for mind and soul. Siddhars have enumerate ways to that are to be followed to maintain the body without being affected by any disease and to maintain sound mind which are called panacea.

கற்பமுறைகள்

"கற்பத்தை யுண்டால் காயம் அழியாது
கற்பத்தினாலே காணலாம் கைலையை
கற்பத்தி னாலே காணலாம் சோதியை
கற்பத்தி னாலே காலையும் கட்டிடே"

- **திருமந்திரம்**

In recent times, pain in the neck is frequently reported from the public as 80% of them are engaged with a profession which makes chronic flexion to the cervical vertebra (Eg: cooks, beedi workers, agriculture labors etc.,

The clinical feature of Ceganavatham is described by Siddhar Yugi in his classification of Vatha disease. Most of the clinical features of this disease are closely resemble that of cervical spondylosis in modern clinical entity.

The incidence of this disease is observed during the study at Government Siddha Medical College, Palayamkottai. The author's choice of drug for the clinical study were,

Vathathirku leghiyam - Kottaipakalavu (6.022gm) twice a day internally.

-Athmaratchamirtham

Pancharka thylam – Externally

-Agathiyar mani ennum vaithiya sinthamani venba-4000

Those drugs were prepared by the author and were tried in 40 cases of Cegana vatham of varied aetiology and the clinical study was undertaken in the post graduate and in the out patient department of sirappu maruthuvam and the follow up study of all the cases was done in the post graduate out patient department.

AIM AND OBJECTIVES

AIM :

Phase II Clinical observation criteria based study of **CEGANA VATHAM** (Cervical Spondylosis) and the drug Choice **VATHATHIRKU LEGHIYAM** (Internal) and **PANCHARKA THYLAM (**External).

OBJECTIVES:

Primary objective:

To evaluate the therapeutic efficacy of **VATHATHIRKU LEGHIYAM** (Internal) and **PANCHARKA THYLAM (**External) in reducing the pain in **CeganaVatham.**

Secondary objective:

- To study the Siddha basic principles like envagaithervugal including neerkkuri and neikkuri .
- To evaluate the safety profile of the trial medicine
- To Evaluate the pharmacological study of trial medicine

REVIEW OF LITERATURE

CEGANA VATHAM

DEFINITION:

The literature of " Yugi Vaidhiya Chinthamani 800" , classified the vatha disease in to 84 types. Cegana vatham is one of the vatha disease. Cegana vatham is a disease that associates with involvement of upper back, which is parallel to cervical spine.

The symptoms include pain present in the neck, pain radiating to the upper limbs, feeling heaviness of the body, giddiness , mental depression, burning sensation of eye and constipation.

AETIOLOGY:

In various siddha literatures, common aetiological factors of vatha disease are described, these aetiological factors are also applicable for the cegana vatham.

IN YUGI VAITHIYA CHINTHAMANI

"தானென்ற கசப்போடு துவர்ப்புறைப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த வண்ணம்
ஆனென்ற வாறினது புசித்த லாலும்
ஆகாயற் றேலது குடித்தலாலும்
பானென்ற பகலுறக்க மிராவிழிப்பு
பட்டினியே மிகவுறுதல் பார மெய்தல்
தேனென்ற மொழியார் மேற்சிந்தை யாதல்
சீக்கிரமாய் வாதமது செனிக்குந்தானே"

"பகரவே வாதமது கோபித்தப்போ
பண்பாக பெண்போக மதுதான் செய்யில்
நகரவே வெகுதூர வழி நடக்கயில்
நளிரான காற்றுமே பனிமேற் பட்டால்
மிகரவே காய்கள் கனிகிழங்கு தன்னை
மிகவருந்தி மீறியே தயிர்தான் கொண்டால்
முகரவே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலும் கணைக்காலும் கடுப்பு உண்டாமே"

- Consumption of bitter taste, astringents, pungent food items excessively,
- Eating previously cooked foot,
- Drinking contaminated water,
- Altered sleep rhytm,
- Excessive starvation,
- Lifting heavy objects,
- Excessive lust,
- Long distance walking,
- Living in cold environment,
- Excess eating of tubers, fruits, curd. etc.,

Kanma vinai is also one of the aetiology of vatham, including cegana vatham.

IN AGASTHIYAR GUNAVAGADAM

"விவரமடா அசதி சன்னி மூளை நோவு
விரிவான மூளையது மிருதுவாகி
அவனிதனில் திடமாகப் போவதாலும்
அப்பனே மூத்திர குண்டிக்காய் வியாதியாலும்
தவமுனிவர் தீர்க்காக்கை மேக ரோகம்
தன்மையுள்ள முத்தண்டு கொடிவியாதி
அவமிலாப் பரிச நரம்பழுத்தங் கண்டால்
அணுகுமடா வாதநோய் ஆகும்பாரே"

- Disease of Spinal cord and Vertebral column,
- Disease of muscles,
- Menorrhagia,
- Mercury and Lead poison.

IN AGASTHIYAR KANMA KANDAM

"நூலென்ற வாதம் வந்த வகைதானேது
நுண்மையாய்க் கன்மத்தின் வகையைக் கேளு
காலிலே தோன்றியது கடுப்பதேது
கைகாலில் முடக்கியது வீக்கமேது
கோலிலே படுகின்ற விருட்சமான

குழந்தை மரந்தன்னை வெட்டல் மேல்தோல்சீவல்
நாலிலே சீவசெந்து கால்முறித்தல்
நல்லகொம்பு தழைமுறித்தல் நலித்தல் காணே.”

- Cutting trees, bark, tender leaves,
- Breaking Animal’s legs,
- Breach of Trust
- Abusing elders, and Priests,
- Damaging charitable properties,
- Discreditable to mother, father and teacher,
- Disrespectful attitude with god,
- Refusing food for destitute and hermits,
- Involvement in theft and murder.

ALTERATION IN UDAL VANMAI

An significant cause of Cegana Vatham is alteration in Udal Vanmai (Body strength). It is described as Kaala Vanmai, Eyarkai Vanmai and Seyarkai Vanmai. Generally in Kaala Vanmai the old age persons are affected. In Seyarkai Vanmai, the conditions like wrong postures, sedentary life style and incomplete foods causes Cegana Vatham.

PATHOLOGY

The alteration in ideality of life style, occupation, and food habits causes the derangements of micro elements in the body (Panchapoothangal). Comparing to other factor, food habits play the direct role.

When these micro elements in the body altered, three humours namely Vatham, Pitham, Kabam get deranged. This on other hand , leads to derangement of seven Udal thathukkal and produces symptoms.

The main aetiological agent of cegana vatham is diet that produce excessive Vayu and on other hand, it cause vitiation of Aahayam, Earth, Water, and Fire. Depending upon the type of agent that affecting , the corresponding Uyir thathu is affected. Vali and Aahayam constitute Vatham. Earth constitute Kabam and fire constitutes Pitham. So when the micro

elements are affected, Uyir thathukkal get affected, which in turn affects Udal thathukkal, that give rise to clinical features of Cegana Vatham.

In Uyir Thathu, when Vatham is affected ;

- ❖ The derangement of Vyanan causes pain in cervical and dorsal spine, pain along upper limbs, scorpion bite like pain and heaviness of the body.
- ❖ The derangement of Abanan causes constipation and
- ❖ The derangement of devathathan cause mental depression.

In Uyir Thathu, when Pitham is affected ;

- ❖ The derangement of Sathaga Pitham causes giddiness.

In Uyir Thathu when Kabam is affected ;

- ❖ The derangement of Tharpagam causes burning sensation of eyes.

Along with this derangement of Uyir Thathus, Udal Thathukkal namely Saaram, Seneer, Oon, Kozhuppu, Enbu, are also affected.

CLINICAL FEATURES

In Yugi Vaidhiya Chinthamani and Pararasasekaram the sings & symptoms of Cegana Vatham is described.

In Yugi Vaidhiya Chinthamani **;**

” கேளுமே கழுத்தின் கீழரைக்கு மேலுங்
கெடியான கரமிரண்டு மிகவே நொந்து
வாளுமே சரீரமெல்லாம் கனத்திருக்கும்
வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்
ஏளுமே யிரண்டு கண்ணு மெரிச்சலாகும்
மேற்றமாய் சலங்தானு மிறுகிக் காணும்
தேளுமே கொட்டினது போற்கடுக்கும்
சகனவா தத்தினிடந் தீர்க்கந் தானே ”

In Pararasasekaram **;**

” கண்டதோர் செகன வாதங் கழுத்தின் கீழரைக்கு மேலும்
மண்டலங் கரமிரண்டு மிகநொந்து கனத்திருக்கும்
மண்டியே திமிர்த்துக் குத்தும் வலி மிகுத்துளைவுண்டாகும்
வண்டமர் குழலினாளே மதியினாலுன்னுவாயே”.

THE CLINICAL FEATURES INCLUDES ;

- ❖ Pain in the cervical region
- ❖ Pain radiating to shoulder and upper limb
- ❖ Heaviness of body
- ❖ Mental depression
- ❖ Giddiness
- ❖ Burning sensation of Eye
- ❖ Constipation
- ❖ Tingling sensation and numbness of upper limbs.

DIAGNOSIS OF CEGANA VATHAM

The following siddha diagnostic methods are used to diagnose the disease.

1. PORIYAL ARITHAL (Sensory organs)

Patient's porigal must be examined by physician's porigal.

IYMPORIGAL	Physiological function
1. Mei	For feeling touch sensation
2. Vaai	For knowing taste
3. Kan	For vision
4. Mooku	For knowing the smell
5. Sevi	For hearing

2. PULANAAL ARITHAL (Five senses)

Patient's pulangal must be examined by physician's pulangal.

IYMPULANGAL	Physiological function
Ooru	Touch (perception of sensation)
Osai	Sound (perception of sound)
Suvai	Taste (perception of taste)
Oli	Vision (Perception of vision)
Naatram	Smell (Perception of smell)

3. VINAATHAL (INTERROGATION)

The physician should interrogate about , patient's name, age, occupation, socio-economical status, diets, history of allergy, history of present and past illness, family and personal history. If the patient's is in the stage of inability to speak, physician should interrogate the details with the person, who is taking care of him.

4. THINAIGAL

The land are classified into five types according to the geographical distribution.

- Kurunji - Kabha and Liver disease are common.
- Mullai - Vatha and Pitha disease are common.
- Marutham - Safest place to maintain good health.
- Neithal - Vadha disease and Liver enlargement are common.
- Paalai - All the three humours may be affected.

Most of the patients came from Maruthanilam. Patients were also reported from Neithal and Kurunji nilangal.

5. PARUVA KAALAM :

One year is divided into six season or kaalam. Each kaalam constitutes two month. They are

S.No.	Paruvakalangal	Kuttram
1.	Kaarkaalam – Aavani and Purattasi (August 16 – October 15))	Vatham ↑ ↑ Pitham ↑
2.	Koothirkaalam - Ayppasi and kaarthigai (October 16 – December 15))	Vatham (-) Pitham ↑ ↑
3.	Munpanikaalam - Maargali and Thai (December 16 – February 15)	Pitham (-)
4.	Pinpanikaalam - Maasi and Panguni (February 16 – April 15)	Kabam ↑
5.	Elavenilkaalam - Aani and Aadi (April 16 – June 15))	Kabam ↑↑
6.	Muduvenilkaalam - Aani and Aadi (June 16 - August 15)	Vatham ↑ Kabam (-)

↑ Thannilai valarchi

↑↑ Vetrunilai valarchi

(-) Thannilai adaithal

According to alteration of thannilai valarchi and vetrunilai valarchi, disease can be diagnosed.

6. UYIR THAATHUKKAL

Uyir thaathukkal means “Life force” Vatham, Pitham, Kabam, which are the humours responsible for the creation, preservation, and desdruction of human body and health. When they are in the state of equilibrium in the ratio (1:1/2:1/4) in which they exit our body remains in a healthy state, but in case of any disturbance in this ratio leads to diseased conditions.

VATHAM

Vatham represents the elements Air & Space.

It is responsible for all movements of mind, and body. Motor and sensory activities are governed by vatham.

S.No.	Vatham	Physiological function	Features in Ceganavatham
1	Pranan	Inspiration and expiration responsible for sneezing coughing and belching	Not affected
2	Abanan	Act with downward movement	Affected constipation present.
3	Viyanan	Helps in various movements of body, responsible for sensation	Affected Restricted neck movements radiating pain in shoulder and arm with tingling sensation.
4	Udhanan	Regulates the higher functions of brain. Responsible for physiological reactions like hiccough and vomiting	Not affected
5	Samanan	Regulates all other vayus	Affected Due to others types of vatham
6	Nagan	Responsible for intelligence helps in opening and closing of eyes	Affected in aged pateints. Acuity of vision is deminished.
7	Koorman	Responsible for lacrimation. Helps in visualization of all things of world.	Affected in aged pateints. Acuity of vision is deminished.
8	Kirukaran	Increase salivation in oral cavity and	Affected (Lack of

		mucosa secretion in nasal cavity, Increase appetite and helps in concentration.	concentration)
9	Thevathathan	Responsible for laziness. Rotation of eyeballs.	Affected (Sleeplessness present due to pain).
10	Thananjeyan	Responsible for tinnitus oedema.	

PITHAM

Pitham is formed by the elements Fire in our body and is responsible for the preservation of health.

S.No.	Pitham	Physiological function	Features in Ceganavatham
1.	Anar pitham	Digests all the ingested particles.	Affected (Indigesion present)
2.	Ranjaga pitham	Increases the blood and gives blood colour	Affected (Anaemia present)
3.	Saathaga pitham	Makes the work to complete what mind thinks to do	Affected neck pain and restricted movement
4.	Prasaga pitham	Gives colours to skin	Not affected
5.	Aalosaga pitham	Responsible for clear vision	Affected in old age peoples.

KABAM

Kabam is formed by elements for strength, joint movements.

S.No.	Kabam	Physiological function	Features in Ceganavatham
1.	Avalambagam	Controls other 4 types of kabam	Affected (santhigam affected)
2.	Klethagam	Moistens the food	Not affected
3.	Pothagam	Helps to know the taste	Not affected
4.	Tharpagam	Gives cooling effect to the eyes	Affected (burning sensation of eye presen)t
5.	Santhigam	Gives lubrication to joints	Affected (pain in cervical region)

7. EN VAGAI THERVU :

En vagai thervu is the unique & special method described in siddha system to diagnose the disease.

"நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவ ராயுதம்"

- **நோய்நாடல் நோய் முதல்நாடல் பகுதி – I**

i) NAADI (Pulse)

By examining the naadi, the condition of humours and the fracture are understood, which is helpful for correct treatment.

In vatha disease, following stages of naadi are seen

Vatha naadi :

"வாதமெனும் நாடியது தோன்றில்
சீதமந்தமொடு வயிறு பொருமல் திரட்சிவாயு
சீதமுறுங் கிராணி மகோதரம் நீராமை
திரள்வாயு சூலைவலி கடுப்புத் திரை ".

-சதகநாடி.

Vatha Pitha naadi :

" பொருளான வாதத்தில் பித்தஞ் சேர்ந்து
கருவான தேகமத்திலுளைச்சல் சோம்பல்
கைகால் தறிப்பு "

-சதகநாடி.

Vatha Kapha naadi :

"பாங்கான வாதத்தில் சேத்தும நாடி
பரிசித்தால் திமிர்மேவு முளைச்சலாகும் ".

-சதகநாடி.

Pitha Vatha naadi :

"பித்தத்தில் வாதமாகில் பிடரியுங் காலுங் கையுங்
குத்தது போலேயாகுங் குறுகி மெய்பதறும் பின்னே ".

-அகத்தியர் நாடி.

Pitha Kapha naadi :

”பித்தத்தில் சேத்துமமாகில் வாய்குளறுமிக்க

.....

பித்தமு மெடுத்துக் கொட்டிப் பிடரியில் நோவதாமோ ”

-அகத்தியர் நாடி.

Kabha Vatha naadi :

”வாட்டிடுஞ் சேத்துமத்தில் வந்திடும் வாதமாகில்

நாட்டிய கால்கள்போல நரம்பெல்லாம் வலித்து நிற்கும் ”.

-அகத்தியர் நாடி.

In all cegana vatham patients, Thondha naadi was noted.

ii) Sparisam:

By sparisam,, temperature, smoothness or roughness, sweet, dryness, hard patches, swelling, tenderness, abnormal growth, nourishment of skin can be felt.

In cegana vatham, there was tenderness in cervical regions for all patients.

iii) Naa:

By nothing the tongue, the colour, dryness, coated, surface, excess, salivation, redness, ulceration, pallor, yellowish discolourations, malignant growth, movement of tongue, and sensation predominant taste is noted.

In cegana vatham , generally no characterized changes is seen in tongue but 4 cases shows pale colour of tongue due to anemia.

iv) Niram:

Colour changes like blackish, yellow, pallor or bluish discolouration is noted. Here there is no specific abnormality in niram.

v) Mozhi:

Slurring, clarity of speech, talk induced by hallucination, undue argument are noted. Here there is no specific abnormality in mozhi.

vi) Vizhi:

Eye is inspected for any abnormal colour, pallor, lacrimation, sub conjectival pallor, accumulation of secretion at angles of eye, bleeding and visual disturbance.

In cegana vatham generally no characterized changes seen, but in 4 cases conjunctival pallor is seen.

vii) Malam:

Consistency, quantity, colour, odour, frequency, is noted. Constipation was noted in 22 cegana vatham patients. All other patients showed normal malam.

viii) Moothiram:

Examination of urine is classified into two types.

a) NEERKURI:

In neerkuri quantity, colour, odour, froth, frequency, retention, deposits, presence of abnormal consistency are noted. It is expressed in following lines,

சிறுநீரின் பொதுக்குணம்

"வந்த நீர்க்கரிஎடை மணம் நுரைஎஞ்சலென்
றைந்தியலுளவவை யறைகுது முறையே"

- **நோய்நாடல் நோய் முதல்நாடல் பகுதி – I**

b) NEIKURI

The predominantly affected humour is assessed by neikuri.

Exposed to bright sunlight, a drop of gingelly oil is allowed to fall on the surface of urine kept in kidney tray.

Observation:

"அரவென நீண்டின.்.தே வாதம்"
ஆழி போற்பரவின் அ.்.தே பித்தம்"
முத்தொத்து நிற்கின் மொழிவதென் கபமே"

- **நோய்நாடல் நோய் முதல்நாடல் பகுதி-I**

If the drop of oil on the surface of oil

i) Spreads like a snake - Vatha disease

ii) spreads like a ring - Pitha disease

iii) Appears like pearl - Kapha disease

In cegana vatham urine is in straw or hay colour.

8. SEVEN PHYSICAL CONSTITUENTS OF BODY

S.No.	Seven physical constituents	Physiological function	Features in Ceganavatham
1.	Saaram	Strengthens the body and mind	Affected
2.	Senneer	Preserves brightness, boldness, power& knowledge	Affected
3.	Oon	Gives structure and shape to the body.	Early stage - Not affected Later stage - Affected
4.	Kozhuppu	Responsible for movement lubricants the joint	Affected
5.	Enbu	Responsible to joint movements	Affected
6.	Moolai	Present inside the bones and gives strength to the bones	Not affected
7.	Sukkilam (or) suronitham		Not affected

9. GNANENTHIRIYAM:

S.No.	Gnanendhiriyam	Physiological function
1.	Mei	Feels the sensation of touch
2.	Naa	Analyses taste
3.	Kan	For vision
4.	Mooku	For smell
5.	Sevi	For hearing

10. KANMENTHIRIYANGAL (Motor organs)

Examination of patient's motor organs.

S.NO	Motor organs	Physiological function
1	Kai	Work done by hands
1.	Kaal	For walking

2.	Vaai	For speech
3.	Eruvaai	For defaecation
4.	Karuvaai	For reproduction
5.	Karuvaai	For reproduction

In cegana vatham mei is affected which leads to pain and numbness.

DIFFERENTIAL DIAGNOSIS

These are certain other vatha disease which resembles the clinical signs and symptoms of cegana vatham. cegana vatham must be differentiated from such disease. They are

1. Kumba vatham
2. Kandakiraga vatham
3. Paanikamba vatham

1.KUMBA VATHAM:

"நவிலவே தோள்மீதுங் கரத்தின் மீது
நலிந்து மெத்தவாகியே நசவுண்டாகும்
கவிலவே கன்னமொடு நயனந் தானுங்
கடுத்துமே விறுவிறுப்பு மெரிவுங் காணும்
துவிலவே துடிப்பாகுஞ் சிரசு தன்னிற்
சுழற்றியே நாபிக்கீழ் வலியு முண்டாம்
அவிலவே யடிநாக்கி லழன்று காணு
மலருமே வருகும்ப வாதந் தானே"

- **யூகி வைத்திய சிந்தாமணி**

The clinical features are

1. Pain in shoulder and upper limbs,
2. Burning sensation in the chest and eyes,
3. Twitching over the region of scalp,
4. Lower abdominal pain
5. Glossitis

2. KANDAKIRAGA VATHAM

"வகையாள குரலதனைப் பற்றி நொந்து
மார்போடு பிடரிதனில் வலியுண்டாகி
நுகரான சரீரமெல்லாம் நொந்த ழலாற்றி
நுணக்கமாய் சுவாசமது புறப்படாமல்
முகையான நாவாலே மூச்சு மாறி
முகத்திலே வியர்வாகி விலாநோ வுண்டாம்
பகையான வன்னத்தைப் பருகொட்டாது
பரிய கண்ட கிராகத்தின் பண்பு தானே".

- **யூகி வைத்திய சிந்தாமணி – 800**

The clinical features are,

1. Pain in the throat, chest and occipital region
2. Breathing through mouth, backache, sweating on face.

3. PAANIKAMBA VATHAM:

"மார்க்கமாய் வாய்வுமாய் மெய்நிறைந்து
வயிறுதனிற் பசியிலா தூணுமற்று
நார்க்கமாய் ஞாலத்து நடக்கையற்று
நடுக்கமாய் கையிரண்டுந் திருமிருண்டாம்
ஊர்க்கமா யுறக்கமில்லா துணர்ச்சி யற்று
உதறியே சரீர மெங்கு முலர்ந்து காணுந்
பார்க்கமாய் வாய்விட்டு அலர்த்தலாகும்
பாணிக்கம்ப வாதத்தின் பாங்குதானே"

- **யூகி வைத்திய சிந்தாமணி**

The clinical features are

1. Anorexia
2. Tingling sensation and numbness of upper limbs
3. Tremors found in upper limbs
4. Sleeplessness
5. Dryness all over the body

NOI NEEKAM (TREATMENT)

The main aim of the treatment is to cure both physical illness and mental illness. Treatment is not only for complete healing but also for the rejuvenation.

It is essential to know the nature of the patient, aetiology, severity and time of occurrence of the disease.

In siddha system the line of treatment consists of the following:

1. Neekam (Treatment)
2. Niraivu (Restoration of wellbeing)
3. Kaappu (Prevention)

NEEKAM

The aim of treatment is based on the following,

a) To bring the three dhosas to equilibrium state.
b) To treat the patients by internal and external medicines.
c) To stabilize seven udal thathukkal and three uyir thathukkal.
d) Diet and advises
e) Sirappu maruthuvam – Thokkanam and yoga
f) Kanma nivarthi

1. **BRING THE THREE DHOSAS IN EQUILIBRIUM:**

Since the siddha system is based on mukkutra theory, the treatment is aimed to bring down the three dhosas to its equilibrium state and thereby restoring the physiological conditions of various thathus.

Vitiation of vatha is the prime factor for “Cegana vatham”.

Kalichal maruthuvam (Purgation) is the best method to correct the vitiated vatham. The following verses reveals the importance of kalichal maruthuvam.

In the first day of treatment 15ml vellai ennai is administrated with hot water at early morning as a kalichal medicine.

2. DRUGS:

Next day onwards the trial drugs were given.

i) INTERNAL MEDICINE:

DRUG -"VATHATHIRKU LEGHIYAM" DOSE - KOTTAIPAKALAVU (6.022gm) Twice a day

ii) EXTERNAL MEDICINE:"PANCHARKA THYLAM" was applied locally over the affected area.

3. **DIET AND ADVISES:**

I) PATHIYAM (DIET REGIMENS):

According to nature of illness and the drug administrated during the course of treatment the patients were advised to follow certain special and specific dietary methods called "PATHIYAM". Therayar explains the importance of pathiyam as below,

"பத்தியத்தினாலே பலன் உண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன் போகும்
பத்தியமே வெற்றி தரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பார்"

- தேரன் வெண்பா

Substance used for neutralizing three humours are:

"ஒன்றிய வாதபித்த கபமிவை யுயரா வண்ணம்
நன்றது கறி களெல்லாம் நாளுமே சமைப்பராய்தோர்
தின்றிடு மிளவு மஞ்சள் சீரக முயர்ந்த காயம்
வென்றி கொள் சுக்கோடேலம் வெந்தியம் உள்ளி சேர்தே"

- ப.கு.சி

To maintain three vital humours in equilibrium one should take food cooked with

- Pepper - Piper nigrum
- Turmeric - Curcuma longa
- Cumin seeds - Cuminum cyminum
- Asafoetida - Ferula asafetida
- Dry ginger - Zingiber officinale
- Cardamom - Elettaria cardamom
- Fenugreek - Trigonella foenum
- Garlic - Allium sativa

சேர்க்கக் கூடிய உணவுகள் (Diet to be included):

காய்கள் (Vegetables)

- கத்தரிப்பிஞ்சு
- முருங்கைப்பிஞ்சு
- அவரைப்பிஞ்சு

கீரைகள் (Greens)

- பொன்னாங்கண்ணி
- மூக்கிரட்டை
- தூதுவேளை
- முடக்கறுத்தான்
- அறுகீரை
- கரிசாலை

பழங்கள் (Fruits)

- மாதுளை
- ஆப்பிள்
- பப்பாளி
- ஆரஞ்சு
- பேரீச்சை
- அத்தி
- நாவல்

அசைவம் (Non-vegetarian diet)

- வெள்ளாட்டுக்கறி
- காடை
- சிறுஇறால் மீன்

SIRAPPU MARUTHUVAM FOR CEGANA VATHAM

1.THOKKANAM

2. YOGA ASANAS

THOKKANAM

Thokkanam is the siddha way of touch therapy. it is the physical manipulation of the body usually done with or without oil application. It is very effective for neurological and musculoskeletal problems. It also promotes mental and physical fitness. According to

siddha, disease in the body occur due imbalance of three humours that is vatham, pitham and kapham which in turn are governed by five fundamental elements – Akayam (Space, vayu (air), Theyu (fire), Appu (water and Mann (Earth. Thokkanam is one of the 32 types of external medicines mentioned in siddha literature. In this technique, the physician uses his hands on the body of the patient in 9 different unique ways with or without using medicated oil with acurative or palliative point of view. The 9 different techniques in thokkanam which makes siddha medicine unique in all aspects. They are

1. Thattal or patting technique
2. Irukkal or tightening
3. Pidithal or holding
4. Murukkal or twisting
5. Kattal or tying
6. Azhuthal or pressing
7. Izhuthal or pulling
8. Mallathuthal or supinating

Benefits of Thokkanam

- Helps to cure vatha disease even without internal medicines.
- Chronic disease like spondylosis, lumbago, disc prolapse, hemiplegia, neurological conditions etc are managed well through thokkanam.
- Improve circulation
- Treats obesity
- Helps in pain relief
- Removes indigestion, constipation and flatulence
- Induce sleep
- Helps maintain normal blood pressure
- Restores vatham, pitham and kapham in normal ratio
- Regulates vatha humour.
- Delays the aging process
- Helps to rejuvenate the body.
- Helps to increase the quantity of oxygen in the cells.
- Helps to prevent wrinkles and maintain the complexion of the skin.
- Tones the muscles

- Helps to keep the joint flexible
- Improves the complexion of the skin
- Improves energy and mental alertness.

Massage (தொக்கணம்)

Thokkanam is a systemic manipulation of the body parts by the by physician (or) physiotherapist.

வாதம் முதலிய முக்குற்ற பிணிகள் உண்டாக்கும் வலியை வெறுங்கையாலோ (அ) தைலம் தடவியோ பிடிப்பது.

தொக்கணத்தி னாலிரத்தந் தோல்ஊ ணிவைகட்கு
மிக்கு சவுக்கியஞ்ச மீரணும்பொ – மெய்க்கதிக
புட்டியுறக்கம் புணர்ச்சி யிவை கதிக்கும்
பட்ட அலைச்சலறும் பார்"

- **தேரன்**

Of these 2 of the methods are very much beneficial in treating cervical spondylosis.

THOKKANAM (THADAVU MURAI)

பிடித்தல்

"பிடித்தலி யங்கும் மைதியி னுந்தகும் பிந்தாதே – எண்ணெ
யுடுத்தது செய்யிற் றசவளி யூனுட லுந்தாதே
வேற்றது செய்யினுஞ் சூசிகை பாரிசை விட்டோடும் - புலி
போற்றது வாயுவு மற்றுது மேனலிப் பொட்டோடும்"

தொக்கணம் செய்யக்கூடிய 5 நிலைகளிலும் செய்யலாம். தைலம் தடவியோ, தடவாமலோ பிடித்துவிட வாத நோய்களுக்கு சிறப்பாக பொருந்தும்.

It is made on the upper fibers of trapezius muscle and the underlying bone.

இழுத்தல் (Pulling)

இழுத்தல் கிடத்த லிருத்த லிரண்டிற்கு மேராமே – என்பில்
முழுத்தது வண்ணுகங் கானமந் தக்கதி சீராமே
உருவுத லென்பது மித்தோழி லேநேரம் பூறாகி – மனம்
வெருவுறு மூன வினைகளை மெய்யடு வேறாகி
வளக்குறு மெண்ணெய் லேயிது செய்வது வல்லாண்மை – உடற்
களக்கஞர் போக்கச் சுளுக்கென வாவதித் தொல்லாண்மை"

இதை தைலத்தை பூசியே செய்யவேண்டும். எலும்புகள் நன்றாய்த் தெரியுமிடங்களிலும், தலையிலும் உருவும்போது மந்தமாக செய்யவேண்டும்.

இதனால் நரம்பில் ஊறி வறுத்துகின்ற வாயுக்கள், பிடிப்புகள், சுளுக்குகள் குணமாகும்.

Done for sternocleidomastoid muscles.

The treatment normally starts with applying the medicated oil on the affected area. It directly acts on lymphatic, muscular, nervous and vascular system.

- Strengthens muscle and skin
- Relaxes whole body
- Regulates nerve function
- Improve blood circulation
- Improve sleep

Through massage, the medicated oil applied permeates through the skin and reaches the tissues under them. It releives pain and tension by stimulation the sensory and motor nerves.

Benefits

It reduces the production of some hormones such as cortisol and nor epinephrine which are responsible for stress.

- Brings fresh oxygen to the affected tissues.
- Swelling and thickening of tissues are reduced.

தடவல் சிகிச்சை

பஞ்ச முடிச்சுத் தடவல்

- கருணாதி முடிச்சு (Atlanto –occipital joint)
- சரமுடிச்சு (C7 – Cervical vertebra)
- துன்னல் முடிச்சு (T12 – Throacic vertebra)
- பதி, பசு, பாச முடிச்சு (Lumbo sacral joint)
- கும்பக முடிச்சு (Sacro –coccygeal joint)

ஆகிய இடங்களைத் தடவ வேண்டும்.

விசுத்தி வர்ம தூண்டல்

1. பிடரி வர்மம்
2. முடிச்சு வர்மம்

இந்த விசுத்தி வர்ம புள்ளிகளை தூண்டி விசுத்தி ஆதாரத்தை தடவுதல் மூலம் வாயு, பூத குறைபாடுகள் சீராக்கப்படுகிறது.

YOGA

Yoga is one of India's wonderful gifts to mankind.

The word "yoga" is derived from Sanskrit origin "Yuj" which means to bind, to join, (or) to apply.

Traditionally philosophers had interpreted this to read "Yoking of all powers of the body, the mind and soul to God".

Another frequently used definition of "Yoga" is that of union of the individual sprit with the universal, since that is its highest aim.

The parallel classical western concept of "Mens sana in corporesano"- a healthy body in a healthy mind has always been recognized and is finding increasing emphasis today.

It has eight clearly defined aspects and in its purest form is a complete system capable of answering all human needs.

Matsyasana

Paschimottaasana

Makarasana

Matsyendrasana

Dhanurasana

Yogamudra

ASANAS

Prior to everything, asana is spoken of as the first part of hatha yoga.

Having done asana, one attains steadiness of body and mind freed from disease and lightness of the limbs.

-Hatha yoga pradipika (1:17)

Asana means a state of being in which one remains physically and mentally steady, calm, quiet and comfortable.

In the yoga sutras of patanjali there is a concise definition of yogasanas. "Sthiram Sukham Asanam", meaning that position which is comfortable and steady. Asanas are specific body position which opens the energy channels and psychic centre. They are tools to higher awareness and provide the stable foundation for our exploration of the body, breath, mind, and beyond.

Our siddhars were well aware of the importance of the spine in relation to disease. Hence they explained many asanas and postures which were designed to make the spine more flexible to prevent spinal mis-alignment, and some may even correct minor spinal mis-alignment. The author had explained about few asanas for ceganavatham patient as a preventive cure.

Vertical stretching asanas:

- Parvatasana (Mountain pose)

Anterior stretching asanas:

- Backward bending postures

ASANAS	COMPLEMENTARY ASANAS
Bhujangasana (Snake pose)	Yoga mudra
Chakrasana (Wheel pose)	Pada hastasana
Matsyasana (Fish pose)	Paschimottasana
Shalabhasana (Lotus pose)	Utthanapadasana
Ustrasana (Camel pose)	Pada hastasana
Dhanurasana (Bow curve pose)	Paschimottasana

Backward bending asanas increase the activity of Jatharagni, which helps to burn and eliminate dross from the physical and subtle bodies. They open up the front vertex of the

chakras. (Chakras are energy centre's along the spine to the top of the head). In terms of the distribution of prana, samana, viyana vayu are stimulated by these types of asanas.

Lateral stretching asanas:

- Konasana (Angle pose)

Spinal twisting asanas:

- Bhu Namanasana (Spinal twist prostration pose)
- Ardha matsyendrasana (Half spinal twist)

The twist imposed on the spine and the whole trunk exercises the muscle, make the spinal coloumn more flexible and stimulates the spinal nerves.

Relaxation asanas:

They are especially recommended for any back/spinal problem.

- Advasana (Reversed corpse pose)
- Makarasana (Crocodile pose)

Procedures of few asanas:

1. Yoga Mudra (Reintegration posture):

Starting position

Sit in Padmasana

Method of practice

Bring the hands to the backside of the trunk and hold the wrist of the right hand by the left hand.

Bending the trunk slowly forward and try to touch the ground with the forehead. If it is not possible try to hold the forehead as nearer to the ground as possible.

Benefits

It allows the spinal column more flexible.

2. Paschimottaasana:

Starting position

Sit on the floor with the legs outstretched, feet together and hands on the knees.

Method of practice

Raising the hands slowly sideward, upward without bending the elbows and hold them above the head.

Bringing the hands slowly downwards, forward without bending the elbow and try to catch the toes with fingers. If it is not possible try to hold the knees.

Bending the body forward and try to touch the knees with the forehead without any strain anywhere in the body.

Benefits

It gives more flexibility to the vertebral column.

It stimulates circulation to the nerves and muscles of spine.

3. Bhujangasana (Snake pose):

Method of practice

1. Lie on the floor with facing downward. keep the legs straight and together place the hands close to the body with palms facing downward.
2. Raising the head, neck and shoulder slowly one by one.
3. Raising the chest as much as possible in such a way that the lower abdomen should keep on in touching with the floor.

Benefits

It strengthens the neck and back muscles

It gives more flexibility to the vertebral column.

4. Dhanurasana (The bow curve pose)

Starting position

Same in Bhujangasana

Method of practice

Folding the right leg slowly at the knee and holding the angle with the right hand. Folding the left leg slowly at the knees and holding the ankle with the left hand. Raising the head, chest, and thigh as high as possible by gradual application of force on the head and legs. Raising the body slowly and making a perfect back arch on the vertebral column as much as possible.

Benefits: Relaxes the spinal column

5. Matsyasana (Fish pose):

Starting position

Sit in Padmasana

Method of practice

Carefully bend backward, supporting the body with the arms and elbows. Lift the chest slightly, take the head back and lower the crown of the head to the floor. Hold the big toes and rest the elbows on the floors. Adjust the position of the head so that the maximum arch of the back is attained.

Benefits

It recirculates stagnant blood in the back, alleviating backache and cervical spondylosis.

6. Gomukhasana (Cow face pose):

Posture

Try to clasp the fingers of both hands behind shoulder blades, sitting with both legs bent in a manner where knees are overlapping.

Benefits

Induce relaxation

Relieves the stiffness of shoulder and neck.

7. **Makarasana (Crocodile posture):**

Method of practice

- This is a lying posture and taking rest.
- Lie flat on the stomach
- Raise the head and shoulders and rest the chin in the palms of the hands with the elbows on the floor.
- Keep the elbows together for a more pronounced arch to the spine, separate the elbows slightly to relieve excess pressure on the neck.

Benefits

Stop cervical bone disorders and to helps one avoid using neck brace.

Release compression of spine nerves.

8. Ardha Matsyendrasana (Half spinal twist):

Posture

Sit with right leg bent at the knee and bring heel under left thigh. Interlock the left heel with right knee.

Inhale and grasp left big toe with right hand fingers, give twist to the whole trunk with exhalation.

Benefits

It reduces the tendency of adjoining vertebrae to develop osteopytes. When practiced with cae, it has proved beneficial for mild cases of slipped disc.

How asanas relief the pain in cegana vatham?

I). Effect on Spinal muscle

Asanas dampens the inflow of sensory impulse to the brain, which causes less stimulation to the emotional brain (Cortex, Hypothalamus, Anterior pituitary and their connectives with Adrenal glands). Therefore, there are less visceral disturbance to disturb attention and concentration. The reduction of sensory input creates a reciprocal chain, relaxing the muscle, inhibition of synapses at the relaxed neuromuscular junction in turn reduce the sensory input further. Thus asanas made musculature of spine as relaxed as possible.

II). Effects on tendon and ligaments

The accentuated curve of the spine makes it supple and mobile. The action on the ligaments and tendons of the spine has important effect on the nervous activity.

III). Effects on nervous system

Acts on the spine by stretching it, generates reflex actions in the vegetative functions and tones the chain of ganglion situated on both sides of the spine.

KANMANIVARTHI:

Kanmam means the deeds which are bad, committed by an individual in this previous birth. So he must expiate it to get better relief before the treatment.

NIRAIVU:

By promoting the awareness about the dietary, seasonal, emotional influence on the disease assurance from disease recovery was given. Lifestyle modification was also advised to them.

KAAPU:

Knowing the cause there by removing it and thus preventing the disease is main aim of siddha system of medicine.

Siddha system emphasizes the purification of thought and activities as mentioned in the siddha text **"Theraiyar Piniyanuga Vithi"** which emphasizes virtueness to be followed even in the daily life activities.

MODERN ASPECT

THE ANATOMY

Vertebral coloum

Our body skeletal system is divided into axial and appendicular skeleton sections. Cranium, vertebral column, ribs and sternum constitutes the axial skeleton.

The vertebral column forms back bone of the body. It is made up of 33 pieces of vertebrae and intervening intervertebral disc. Length is about 60-70 cm. The vertebral column which lodges and protect the spinal cord, its meanings in a canal within it is called as vertebral canal.. It supports the body weight and transmits it to the ground through the lower limbs.

The segments can be divided into

cervical	-	07
Thoracic	-	12
Lumbar	-	05
Sacral	-	05
Coccygeal	-	04

The general features of the vertebrae:

The Vertebrae can be divided into two parts. Vertebral body (ventral part), Vertebral arch (dorsal part).

Vertebral bodies is cylindrical and large in size. The vertebral arch has two pedicles, seven processes and two laminae. The laminae are vertical plate like structures fuses together to form spinnus process. The articular processes are four in number, bearing the articular facts and articulate with the adjacent vertebrae. Transverse processes project laterally from the junction of pedicle and laminae. In thoracic region they articulate with ribs.

Intervertebral discs:

Intervertebral disc are fibro cartilaginous in nature. The central part is avascular. They are thicker in lumbar region.

The intervertebral disc acts as

- As a shock absorber.
- As a spacer: It maintains its height which allows the segmental nerve roots to exits each spinal level without compression.

- As a hydraulic cylinder: Annular fibres serve a containment function to prevent the nucleus from bulging or herniating.
- As a motion unit: The elasticity of the disc allows motion coupling. So that the spinal segment can flex, rotate and bend all side.

Cervical vertebrae:

The cervical segment of vertebral column contains 7 vertebrae.

The first second and the seventh are atypical and the third to sixth are typical.

They are smaller and delicate than the thoracic and lumbar vertebrae.

All the cervical vertebrae have a foramen in the transverse process known as foramen transversarium.

Features of Typical cervical vertebrae:

Body:

It is small and oval. Its superior surface is can care transversely with upward projecting lips on each side and its inferior surface is saddle shaped.

Vertebral foramen:

It is larger than the body and triangular.

Vertebral Arch:

1) Spine:

It is short and bifid.

II) Laminae:

These are long and narrow being thinner above than below.

III) Pedicles:

These are short and directed downwards from the middle of posterolateral parts of the body.

IV) Articular facets:

The superior and inferior articular processes project laterlly at the junction of the pedicle and the lamina.

V) Transverse process:

The transverse process lies laterally from the junction of pedicle and laminae to end in posterior tubercle.

The Atypical Cervical vertebrae:

1. **Atlas**:

   It is the first cervical vertebrae it support the heads. It has no body and spine. It has anterior and posterior arch, right and left lateral mass and transverse processes.

   The Posterior aspect bears an oval facet which articulate with dens. its anterior arch bears an anterior tubercle in the anterior aspect. The posterior surface of the posterior arch has a median posterior tubercle. The two lateral masses bear an elongated superior articular facet for atlanto – occipital joint and an inferior articular facet for atlanto – axial joint.

2. **Axis:**

   The axis has a tooth – like process projecting from the body is known as the dens or odontoid process. It has circular facet anteriorly articulating with atlas. There are two articular facet on either side of the dens on the upper surface of the body. The laminae are thick. The spine is large and bifid terminating in two rough tubercle. The transverse process is small and represent the true posterior tubercles only.

3. **The seventh cervical vertebrae**:

   It is also known as the vertebral prominence. The transverse process does not posses anterior tubercle. The foramen transversarium is small or absent. It transmits accessory vertebral vein only. The spine is long and non-bifid.

Joints of the Neck:

1. **Atlanto – occipital joint:**

It is a synovial joint of the condyloid variety.

Movements:

Flexion, Extension, lateral bending.

2. Atlanto – axial Joint:

It comprises three joints.

(i) A Pair of lateral atlanto – axial joints.

(ii) Median atlanto – axial joint.

Movement:

Rotatory movements around a vertical axis occur in this joint.

3. The unco vertebral Joint: (LUSCHKA'S JOINT)

Luschka's Joints are not true synovial Joint. Which develop as a result of degenerative changes in the edges of the disc in early adult. Luschka's Joints are important because

(a) They are important site of osteophyte formation.

(b) The ostrophytes may compress the cervical nerves.

Blood supply of the Vertebral column:

The vertebrae and longitudinal muscles attached to them are supplied by segmental arteries. The arteries give multiple small branches to the vertebral bodies. The extensor muscles of the neck are supplied by the occipital the deep cervical and the transverse cervical arteries.

Venous drainage:

The internal vertebral venous plexus lies within the vertebral canal, but outside the spinal dura. It received tributaries from

(i) The Vertebrae through the basilo vertebral veins.

(ii) The meninges and the spinal cord.

Palpable parts of cervical vertebrae:

i. The transverse process of C1 through the anterior border of sterno cleidomastoid immediately below the tip of the mastoid process.

ii. The spine of C2 is in the nape of the neck 5cm below the external occipital protuberance.

iii. The spine of C7 Where the collor bone crosses the posterior medium line of the neck.

Movements of the Vertebral column:

The greater thickness of the disc in the cervical region compared with thoracic region is associated with the greater individual range of movements occurring in those regions.

Flexion, Extension, lateral flexion and rotation are possible in vertebral column.

MUSCLE AND NERVE SUPPLY INVOLVED IN MOVEMENTS:

Movements	Muscles	Nerve Supply
Flexion	Sternocleidomastoid	Accessory ventral rami of cervical spinal nerves C2, C3, C4
	Longus Capitis	Cervical Ventral rami C1-C3
	Longus coli	Cervical ventral rami C2-C6
	Rectus Capitis anterior	C1 Ventral Ramus
Extension	Trapezius	Accessory Nerve
	Erector spinae	Dorsal rami
	Rectus capitis posterior major and minor	Dorsal Rami C1
	Oblique capitis superior	C1 – Dorsal ramus
Lateral flexion and rotation	Scalene	Cervical ventral rami C3-C8
	Sternocleidomastoid	Acessory, ventral rami of cervical spinal nerves C2,C3,C4.
	Rectus Capitis	C1 – ventral ramus
	Splenius	Cervical dorsal ramus.
	Longus coli	Cervical ventral rami C3-C8
	Levator scapulae	Cervical ventral rami C3,C4,C5
	Longismus obliques capitis superior and inferior	C1 Dorsal ramus

CERVICAL SPONDYLOSIS

DEFINITION

Cervical spondylosis is a disorder characterised by degenerative changes in intervertebral disc, with subsequent changes in the bones and soft tissues. Spondylosis is usually asymptomatic. Symptoms are usually manifested of encroachment of local neural elements such as cervical nerve roots, spinal cord, vertebral artery (or) sympathetic nerves

EPIDEMIOLOGY

Cervical spondylosis is the most frequent cause of spinal cord disturbance in patients older than 55 years.

On the basis of radiological findings ,90% of men older than 50 years and 90% of women older than 60 years have evidence of degenerative changes in the cervical spine.

Both sex are affected equally. Cervical spodylosis usually starts earlier in men than women.

LOCATION:

Generally the C5 & C6 roots are most commonly affected by cervical spondylosis as a result of increased mobility at the **C_5 - C_6 & C_6 – C_7** levels.

Acute disc lesions are seen most often at the C7 level followed by C6 level.

Cervical Spondylosis

AETIOLOGY

1. **Degenerative Causes**

There are primary and secondary.

a) **Primary – Senility**

- Genetic factors
- Metabolic factors
- Manual Labour

b) **Secondary – Osteo arthritis**

- Rheumatoid arthritis
- Metastatic carcinoma
- Lymphoma of spine
- TB spine

2. **Trauma**

- Automobile accident with whiplash injury
- Atheletic injury
- Sudden jerk on the arms during falling down
- Disc prolaps or previous injury

3. **Occupational cause**
4. **Hereditary factors**

- Congenital narrowing of the cervical spinal canal.
- Segmental defets – Hemi vertebra, Fushed Vertebrae.

5. **Acquired narrowing of cervical spinal canal due to**
   - Osteophytes
   - Ossified posterior longitudinal ligament.
   - Facet joint hypertrophy (results foraminal stenosis and compression of root of radicular artery).
   - Hypertrophied ligamentun flavum (compress the cord during extension).

Pathophysiology

- Intervertebral discs lose hydration and elasticity with age and these leads to cracks and fissures. The surrounding ligaments also lose their elastic properties and develop traction spurs. As the disc space narrows, the annulus bulges and facet override. This change, in turn, increase motion at that spinal segment and further hastens the damage to the disc, annulus fissures and herniation may occur. Acute disc herniation may complicate chronic spondylotic changes.
- As the annulus bulges, the cross sectional area of the canal is narrowed. This effect may be accentuated by hypertrophy of the facet joints (posterioly) and of the ligamentum flavum, which becomes thick with age. Neck extension causes the ligaments to fold inward, reducing the unterioposterior (AP) diameter of the spinal canal.
- As disc degeneration occurs, the uncinate process ovverrides and hypertrophies compromising the ventrolateral portion of the foramen. Facet hypertrophy decreases the dorsolateral aspect of the foramen. this change contributes to the radiculopathy that is associated with cervical spondylosis. Marginal osteophytes begin to develop.

PATHOLOGY

The early changes to be erosion and flaking of cartilaginous surface with advance of disease. Cleft appear within the cartilage at the right angles to the surface, these claft may penetrate to the subchondral bone producing cartilage fibrillation. Sometimes fragment of cartilage break off to create joint mice. This result is growth of blood vessels from the subchondral bone which is dense, smooth, glittering, to ivory. This is known as eburnation. The loss cartilage accounts for the thinning of joint space which is seen radiographically.

Osteophyte development from margin of articular cartilage may extend to ligament and capsular attachments. These are called "Bony spurs" of OA. These bony spurs accounts for nodules known as Heberden's nodes.

Common clinical syndromes associated with cervical spondylosis include the following:-

1. HEAD ACHE

Head ache is a common symptom. It's usually located in occipital region.

2. CERVICAL PAIN

- Chronic sub occipital head ache may be present.
- Pain may radiate to the occipital, shoulder, scapula (or) arm.
- The pain, which is worse when the patient is in certain position, can interfere with sleep.

3. AUTONOMIC SYMPTOMS

Vertigo, flushing, tinnitus, visual blurring are present. These are mediated by sympathetic disturbance to the sinuvertebral nerves from stellate ganglion.

4. CERVICAL RADICULOPATHY

Compression of Cervical nerve roots leads to ischemic changes that cause sensory dysfunction (Radicular pain) and motor dysfunction (weakness). Radiculopathy most commonly occurs in persons aged 40-50yrs. An acute herniated disc or chronic spondylotic changes can cause cervical radiculopathy and myelopathy. The C6 root is the most commonly affected one because of the predominant degeneration of the C5-C6 interspace. The next common sites are at C6-C7. There is also referred pain and tenderness along the medial border of the scapula.

5. CERVICAL MYELOPATHY

It may be precipitated by a large central disc herniation but is more commonly the result of spondylotic changes superimposed on a congenitally narrowed canal. Dorsomedial herniation of disc and the development of transverse bony bars or posterior osteophytes may results alone or in combination with pressure on the spinal cord or the anterior spinal artery which supplies the anterior 2/3 of the cord.

It has an insidious onset, which typically becomes apparent in persons aged 50-60 years.

- Upper motor neuron signs develop in the limbs with spasticity of the legs.
- Sensory loss in the upper limbs is common.

- Tingling and numbness with progressive clumsiness.
- Involvement of the sphincter is unusual at presentation.

THE SITE OF SENSORY DISTURBANCES WITH INDIVIDUAL ROOT

Nerve root	Dislevel	Symptoms
C3	C2-C3	Pain and numbness in the back of the neck mastoid process, and pinna of ear.
C4	C3-C4	Pain and numbness in the back of the neck, levator scapulae and anterior chest.
C5	C4-C5	Pain in the neck, Tip of the shoulder, anterior arm, numbness over middle of the body, deltoid muscle.
C6	C5-C6	Pain in the neck, shoulder, medial border of the scapula, lateral arm, dorsal forearm, numbness in tip of thumb or on dorsum of hand over first dorsal interosseus muscle.
C7	C6-C7	Pain in the neck, shoulder, medial border of scapula, lateral arm, dorsal forearm, sensory change in index and middle finger.
C8	C7-T1	Pain in the neck, medial border of scapula,medial aspects of arm and forearm. Sensory change in the ring and little fingers.

THE MOTOR SYMPTOMS AND SIGNS

(INCLUDING REFLEXES)

Nerve Root	Disc level	Weakness-Reflex change
C3	C2-C3	Not readily detectable weakness or reflex change except by EMG.
C4	C3-C4	Not readily detectable weakness or reflex change except by EMG.
C5	C4-C5	Weakness of extension of arm and shoulder particularly above 90^{o},wasting of deltoid muscle ,no reflex change.
C6	C5-C6	Weakness of biceps muscle, diminished triceps reflex.
C7	C6-C7	Weakness of triceps muscle, diminished triceps reflex.
C8	C7-T1	Weakness of triceps and small muscles of hand.No reflex change.

PHYSICAL EXAMINATION

1. Spurling sign

Radicular pain is exacerbated by extension and lateral bending of the neck toward the side of the lesion. Which result in further foraminal compromise.

2. Lhermitte's sign

The generalized electric shock sensation is associated with neck extension.

3. The elbow flexion test

Fully flex the elbow and observe for ulnar nerve distribution.

4. Shoulder abduction test

Relief of cervical radiculopathy by abduction.

5. Phalynx wrist flexion test

Full passive flexion of the patients wrist for 30-60 seconds and looking for reproduction or worsening of worsening of finger dysthesiasis

6. Adson's test

Turns his head to the involved side, raises the chin and holds a deep inspiration and while the ipsilateral radial pulse is palpated with the arm slightly abducted from the side if pulse diminishes test positive for thoracic outlet syndrome.

7. Roo's test

The patients is asked to abduct the shoulder 90^0, flex the elbow 90^0 and open & close the hands slowly for 3 minutes.

i) Hand pallor
ii) Diminished pulse
iii) Ulnar dysthesias

If these are positive suggest thoracic outlet syndrome.

Complications

1. Pseudo arthrosis
2. Graft displacement.
3. Neurological injury

PATHOLOGIES THAT MIMIC CERVICAL SPONDYLOSIS

1. Hereditary spastic paralysis
2. Amyotropic lateral sclerosis
3. Intrinsic & Extrinsic neoplasia
4. Multiple neoplasia
5. Spinal infarction
6. Thoracic outlet syndrome
7. Vitamin B12 deficiency

INVESTIGATION:

1. **Plain – x ray** of cervical spine antero posterior and lateral views.
   - Intervertebral disc space narrowing
   - Osteophytic changes
   - Altered Lordosis
   - Degeneration in facet and vertebral joints.
   - Foraminal stenosis, central stenosis.
   - Sclerosis in the vertebrae.
2. **MRI - (MAGNETIC RESONANCE IMAGING:**

   To asses cervical canal diameter,to find out severity of the compression
3. **CT – SCAN (Computerised Tomography)**
   - Confirms degenerative changes
   - May demonstrate posterior osteophytes and disc herniation.
4. **CT – MYELOGRAPHY:**

   Useful for localisation of cord compression
5. **EXAMINATION OF CSF**

   Very high level of protein.

INSTRUCTION:

- Do not getting look down to read (or do any other work). Bring the reading materials to the eye level.
- All the neck movements can be performed with practice, by using trunk movements.
- While lying on sides, head should be in neutral position.
- Use low level pillow supporting the head and neck. Pillow line up to the shoulders level.

PROGNOSIS:

Cervical spondylosis progresses slowly. By the using the pathological conditions of the spine, spinal cord and the nerve roots the spondylosis can be assessed. Improvement can be felt with some of the visible changes with drug treatment. In complicated cases improvement is not possible. Long history of suffering multiple disc lesion and in recompression of spinal cord may adversely affect the prognosis.

MATERIALS AND METHODS

The clinical study on Cegana vatham was carried out in the post graduate Sirappu Maruthuvam department of, Government Siddha Medical College, Palayamkottai. In this study 40 patients (who satisfy the inclusion criteria and exclusion criteria) were treated as OP and IP patients.

Selection of the patients

Age

Between 20 years and 60 years

Sex

Male and Female

Clinical findings

The patients were selected on the basis of the following clinical findings.

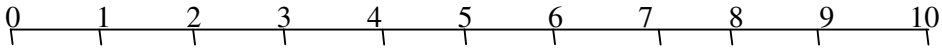
1. Pain, stiffness an restricted movements in the neck.
2. Tingling sensation and numbness in the upper limbs.
3. Radiating pain in the upper limbs
4. Feeling of heaviness in the body and weakness of the limb
5. Constipation
6. Mental depression
7. Burning sensation of eyes.

The detailed history was taken from the patient about

1. Occupation
2. Social economic status
3. Psychological condition

PAIN ASSESSMENT

UNIVERSAL PAIN ASSESSMENT SCALE



A.0 : No Pain

B. 1-3 : Mild pain

C.4-6 : Moderate pain

D.7-10 : Severe pain

Reference: Clinical Manual for Nursing Practice. (National Institute of Heatlth Warren Grant Magnuson Clinical center

GRADATION:

Grade 1: Fit for all activities to do their work without support (Normal)

Grade 2: Mild Pain and Mild restriction of Movements

Grade 3: Moderate Pain and Moderate restriction of Movements

Grade 4: Severe Pain and Severe restriction of Movement

Diagnosis

The diagnosis was made by following siddha diagnostic methods. Nilam, kaalam, poriyal aridhal, pulanal arithal, vinaadhal, mukkutra nilaigal, udal thathukal nilai and envagai thervugal and the diagnosis of cegana Vatham were obtained which correlated with modern diagnosis of cervical spondylosis by the x-ray findings.

The x-ray findings

Exclusion criteria

- Cervical rib
- Trauma
- Spina bifida
- Diabetes mellitus
- Ankylosing spondylosis
- Tuberculosis in spine
- Cardiac disease
- Pregnant women and lactating mothers
- Neoplasms
- Patients with any other serious systemic illness
- Congenital anomalies of spine.

Investigation

The following investigations were done in all selected patients in the laboratory of Government Siddha Medical College, Palayamkottai.

Blood

- Total WBC count
- Differential WBC count

- Erythrocyte sedimentation rate
- Hemoglobin estimation
- Estimation of blood sugar
- Estimation of blood urea
- Estimation of serum cholestrol

Urine

- Albumin
- Sugar
- Deposit

Radiological Investigations

X-Ray cervical spine

- AP-view
- Lateral view
- Oblique view (if needed)

Treatment

Vellai ennai 10ml at morning with hot water was given on the first day of treatment.

All the patients were treated with the following medicine.

1. VATHATHIRKU LEGHIYAM

   Kottaipakalavu (6.02gm)

2. PANCHARKA THYLAM – 30ml

   As external application

Thokkanam and Yoga asanas were applied as the balancing therapy.

All the patients were advised to follow dietary regimen (or) Pathiyam.

The Bio-chemical analyses were done in the Department of Bio-chemistry of Government Siddha Medical College, Palayamkottai.

RESULTS AND OBSERVATION

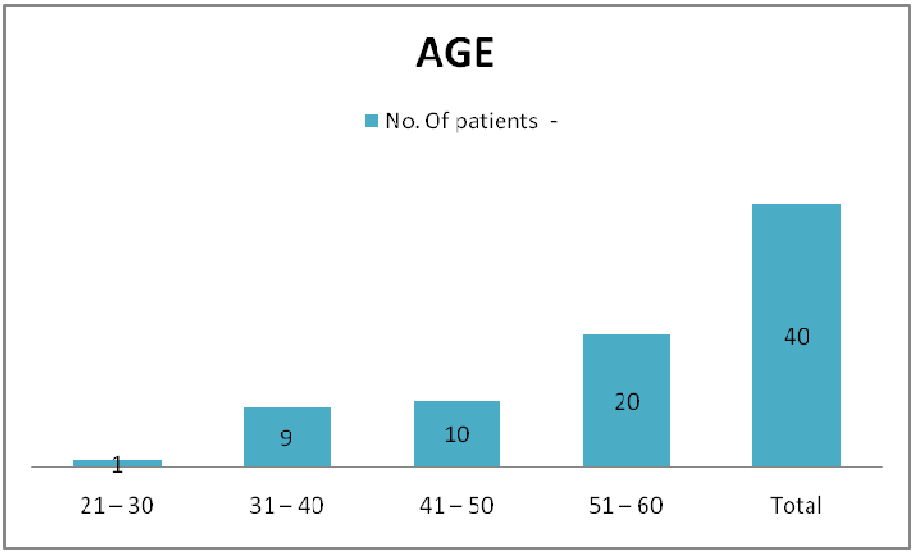
For the clinical study 40 patients were selected and treated in PG-III Sirappu Maruthuvam Department, Government Siddha Medical College and Hospital, Palayamkottai. Results were observed with respect to the following criteria.

1. Age distribution
2. Sex distribution
3. Kaalam
4. Thinai
5. Paruva kaalam
6. Etiological Factors
7. Occupation
8. Clinical Manifestations
9. Duration of illness
10. Disturbance in vadha
11. Disturbance in pitha
12. Disturbance in kabha
13. Udal Thathukkal
14. Envagai Thervugal
15. Pulse reading (Naadi)
16. Neikuri
17. Provocative test
18. Progress chart
19. Patients treated only with trial drugs
20. Trial drugs along with complementary therapy (Thokkanam)
21. Trial drugs along with complementary therapy (Yoga asanas)
22. Effect of Trial drug along with complements therapies.
23. Comparison between effective of trial drug and trial drug with complementary therapies
24. Effect of therapy

1. AGE DISTRIBUTION

Table 1. Illustrates the age distribution

S.no	Age	No. Of patients	Percentage(%)
1	16 – 20	-	0%
2	21 – 30	1	2.5%
3	31 – 40	9	22.5%
4	41 – 50	10	25%
5	51 – 60	20	50%
	Total	40	100%



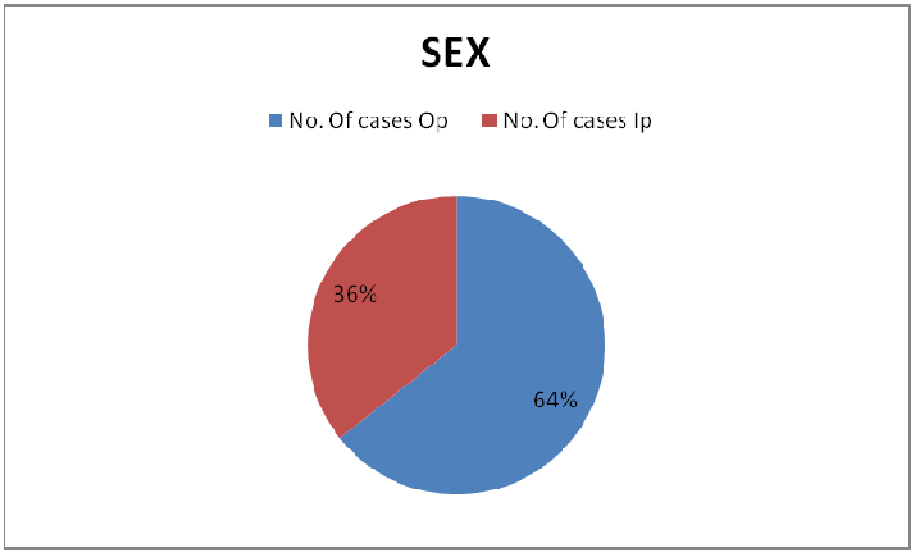
Inference:

Among the 40 patients, in the highest incidence was in the age between 51-60, lowest incidence was in the age between21-30.

2. SEX DISTRIBUTION

Table 2. Illustrates sex distributions in relative percentage.

S.no	Sex	No. Of cases		Percentage
		Op	Ip	
1	Male	9	5	35%
2	Female	16	10	65%
3	Total	25	15	100%



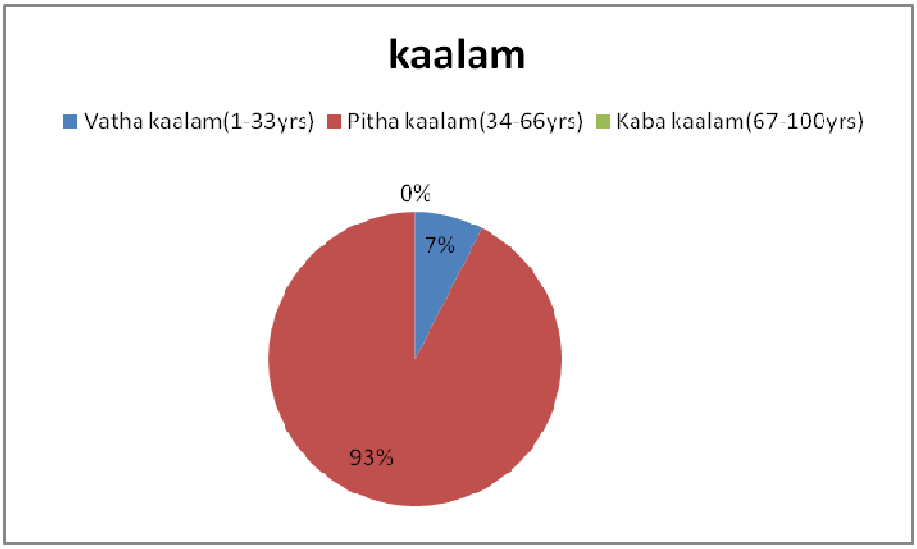
Inference:

Out of 40 patients ,64% were females and 36% were males.

3.KAALAM

Table 3. Illustrates the kaalam

S.no	Kaalam	No. Of patients	Percentage(%)
1	Vatha kaalam(1-33yrs)	3	7.5%
2	Pitha kaalam(34-66yrs)	37	92.5%
3	Kaba kaalam(67-100yrs)	-	-



Inference:

Out of 40 patients,

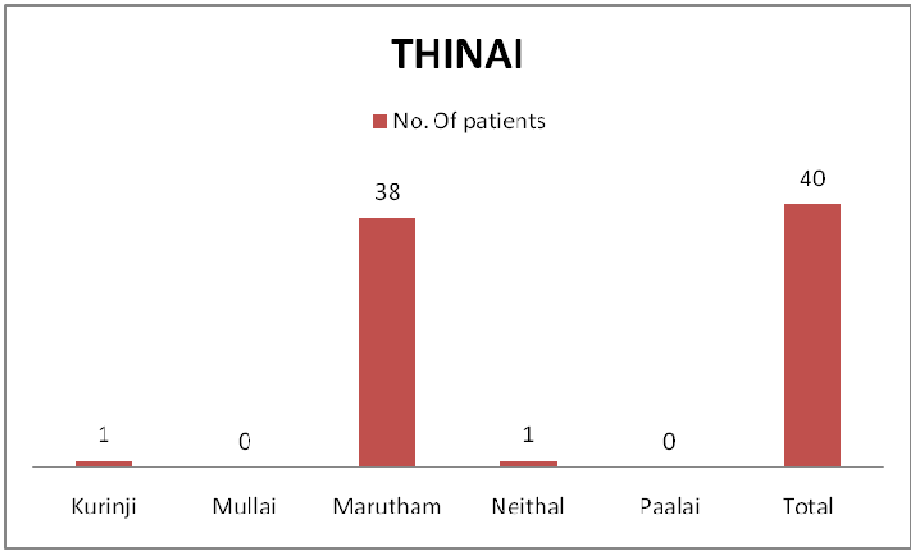
7.5% cases were in the vatha kaalam

92.5% cases were in the pitha kaalam.

4. THINAI (THE HABITAT OF THE PATIENTS)

Table 4. Illustrates the thinai

S.no	Thinai or Land	No. Of patients	Percentage(%)
1	Kurinji	1	2.5%
2	Mullai	-	-
3	Marutham	38	95%
4	Neithal	1	2.5%
5	Paalai	-	-
6	Total	40	100%



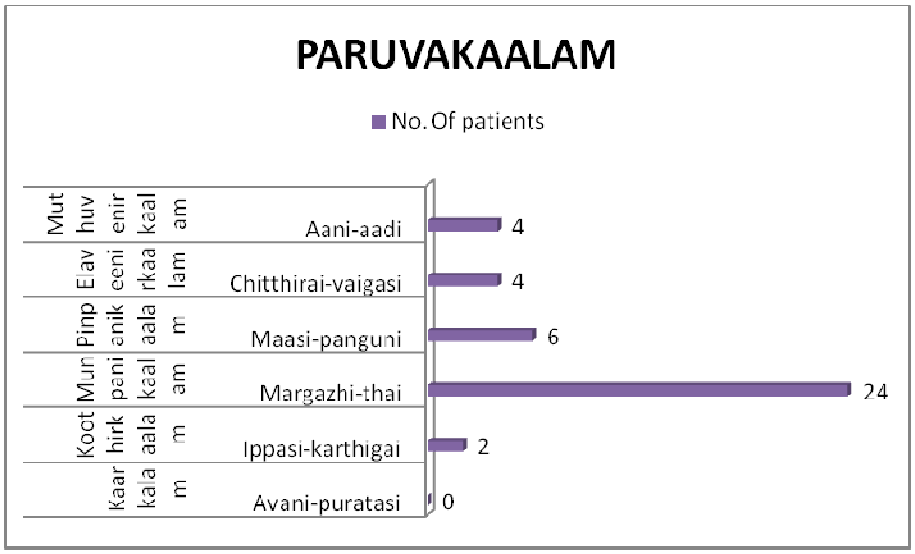
Inference:

Among the 40 patients, 2.5% were from kurinji,95% were from marutham, 2.5% were from neithal

5. PARUVAKALAM

Table 5. Illustrates the Paruvakalam

S.no	Paruvakalam	Month	No. Of patients	Percentage(%)
1	Kaarkalam	Avani-puratasi (15 aug – 14 oct)	-	-
2	Koothirkaalam	Ippasi-karthigai (15 oct – 14 dec)	2	5%
3	Munpanikaalam	Margazhi-thai (15 dec – 14 feb)	24	60%
4	Pinpanikaalam	Maasi-panguni (15 feb – 14 apr)	6	15%
5	Elaveenirkaalam	Chitthirai-vaigasi (15 apr – 14 jun)	4	10%
6	Muthuvenirkaalam	Aani-aadi (15 jun– 14 aug)	4	10%



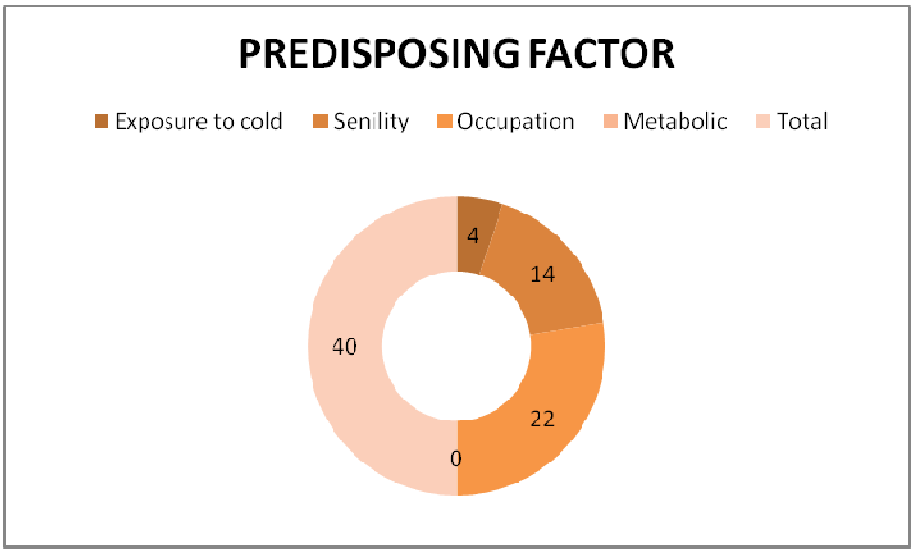
Inference:

Among 40 cases, 60% were admitted in munpanikaalam ,15% of patient were admitted in pinpanikaalam, 10% of patient admitted in elavenirkaalam,10% patient admitted in muthuvenirkaaalam, and 5% patient admitted in koothirkaalam

6. DISTRIBUTION BASED ON ETIOLOGICAL FACTORS

Table 6. Illustrates etiological factors

S.no	Precipitating factors	No. Of patients	Percentage(%)
1	Exposure to cold	4	10%
2	Senility	14	35%
3	Occupation	22	55%
4	Metabolic	-	-
5	Total	40	100%



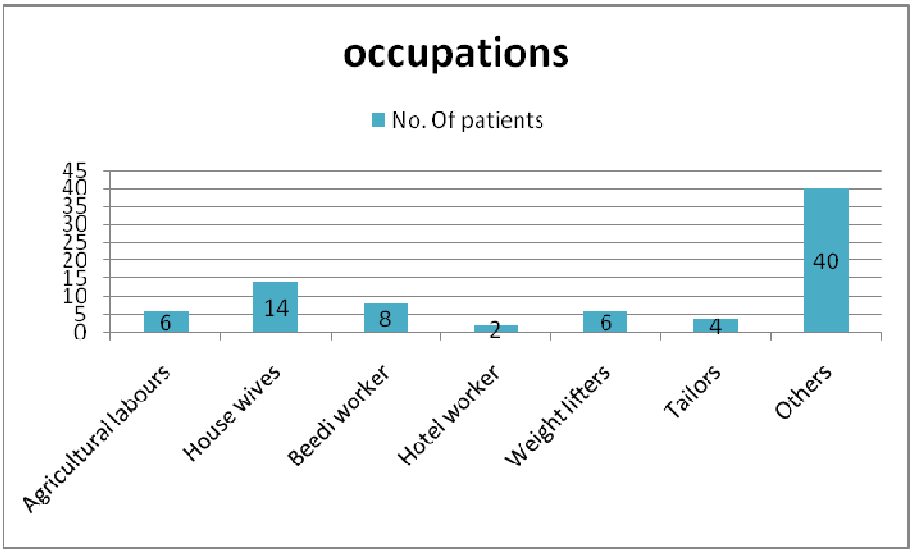
Influence

It was noted while taking the history of the patients that ceganavatham was caused mainly (55%)due to the nature of the occupation .The remaining were due to other factors like to senility and exposure cold.

7. OCCUPATION

Table 7. Illustrates occupation

S.no	Occupation	No. Of patients	Percentage(%)
1	Agricultural labours	6	15%
2	House wives	14	35%
3	Beedi worker	8	20%
4	Hotel worker	2	5%
5	Weight lifters	6	15%
6	Tailors	4	10%
7	Others	40	100%



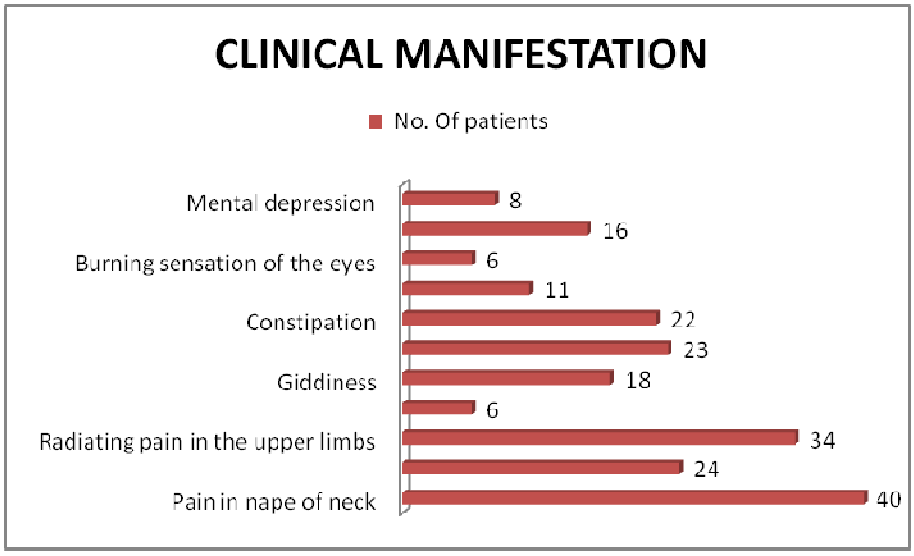
Inference

Out of 40 cases, in this study the rate of incidence is higher in home maker (35%) which includes Beediworkers (20%),agricultural labours and weight lifters (15%),tailors (10%),hotel workers (5%).

8. CLINICAL MANIFESTATION

Table 8. Illustrates the clinical manifestation

S.no	Udal kattukal	No. Of patients	Percentage(%)
1	Pain in nape of neck	40	100%
2	Stiffness in the neck	24	60%
3	Radiating pain in the upper limbs	34	85%
4	Headache	6	15%
5	Giddiness	18	45%
6	Numbness in upper limb	23	57.5%
7	Constipation	22	55%
8	Feeling of heaviness of the body	11	27.5%
9	Burning sensation of the eyes	6	15%
10	Weakness of the upper limbs	16	40%
11	Mental depression	8	20%



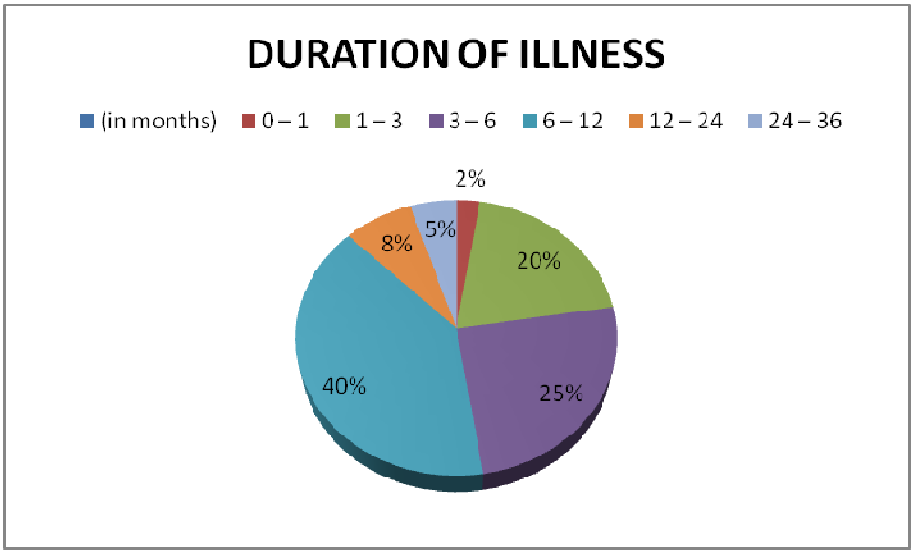
Inference:

Among the 40 cases, all of them had pain in the nape of neck and 60% of patients had stiffness in neck and 85% of patients had radiating pain in upper limb 57.5% of patients had numbness in the upper limb and 45% of patients had giddiness.

9. DISTRIBUTION ACCORDING TO THE DURATION OF ILLNESS

Table 9. Illustrates Distribution according to the duration of illness

S.no	Duration of illness (in months)	No. Of patients	Percentage(%)
1	0 – 1	1	2.5%
2	1 – 3	8	20%
3	3 – 6	10	25%
4	6 – 12	16	40%
5	12 – 24	3	7.5
6	24 – 36	2	5



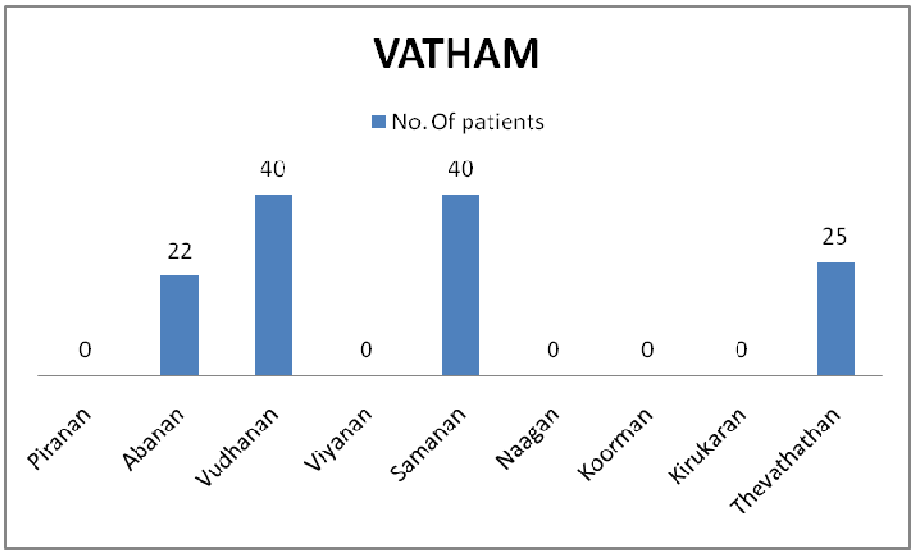
Inference

From the present study it was studied that the disease Cegana vatham reflected its symptoms mostly over a period of 6-12 months which was confirmed during the history taking while 40% of the patients reported the data.

10. DISTURBANCE IN VATHAM

Table 10. Illustrates disturbance in vatham

S.no	Vatham	No. Of patients	Percentage(%)
1	Piranan	-	-
2	Abanan	22	55%
3	Vudhanan	40	100%
4	Viyanan	-	-
5	Samanan	40	100%
6	Naagan	-	-
7	Koorman	-	-
8	Kirukaran	-	-
9	Thevathathan	25	62.5%
10	Thananjayan	-	-



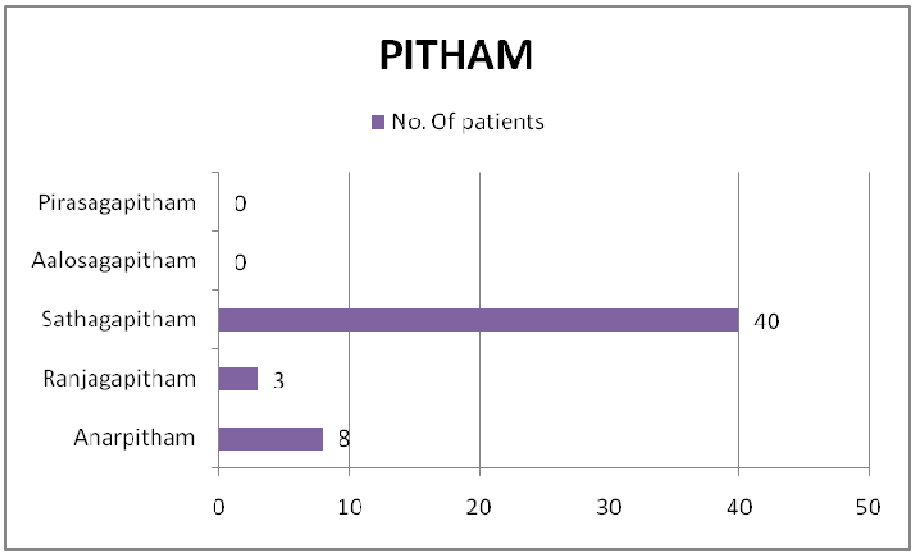
Inference

Among the 10 types of vatha, Samanan and viyanan were affected in all the cases (100%). Abanan was noted to be deranged in 55% and Devathathan was abnormal in 62.5% .

11. DISTURBANCES IN PITHAM

Table 11. Illustrates disturbances in pitham

S.no	Pitham	No. Of patients	Percentage(%)
1	Anarpitham	8	20%
2	Ranjagapitham	3	7.5%
3	Sathagapitham	40	100%
4	Aalosagapitham	-	-
5	Pirasagapitham	-	-



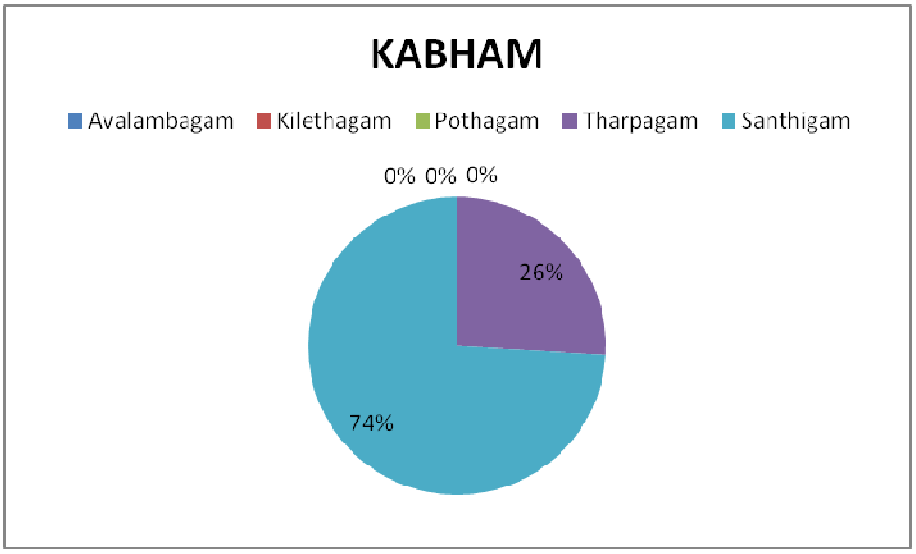
Inference

The five types of pitham were analyzed in all 40 cases, Sathaga pitham was altered in all cases (100%) evidenced as difficulty in handling their regular duties because of pain and stiffness in neck and upper limb. Ranjaga pitham was affected in 7.5% patients denoting low haemoglobin count.

12. DISTURBANCES IN KABAM

Table 12. Illustrates disturbances in kabam

S.no	Kabam	No. Of patients	Percentage(%)
1	Avalambagam	-	-
2	Kilethagam	-	-
3	Pothagam	-	-
4	Tharpagam	14	35%
5	Santhigam	40	100%



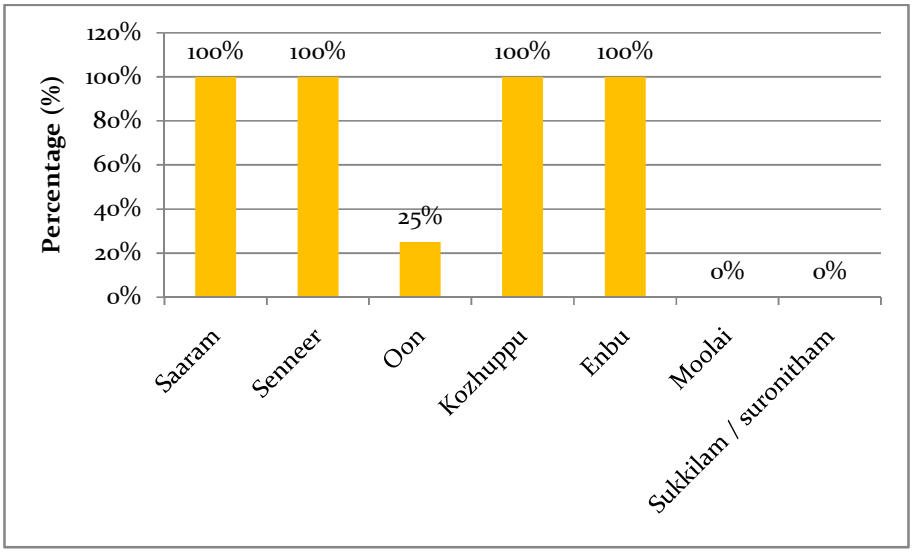
Inference

Santhigam was observed to be affected in all the cases. Tharpagam was abnormal in 35% of the cases.

13. INVOLVEMENT OF UDAL KATTUKAL

Table 13. Illustrates the involvement of udal kattukal

S.no	Udal kattukal	No. Of patients	Percentage(%)
1	Saaram	40	100%
2	Senneer	40	100%
3	Oon	10	25%
4	Kozhuppu	40	100%
5	Enbu	40	100%
6	Moolai	0	-
7	Sukkilam / suronitham	0	-



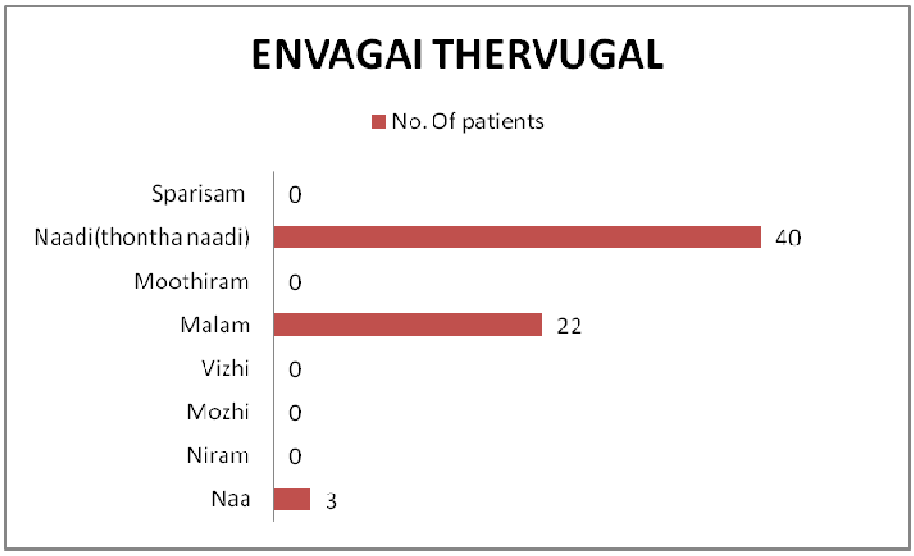
Inference

It was diagnosed during the study that among the seven thathus saram,senneer, kozhuppu, Enbu were affected in 100% of the cases, and Oon had 25% cases were affected

14. CONDITION OF ENVAGAI THERVUGAL

Table 14. Illustrates the condition of envagai thervugal

S.no	Envagai thervugal	No. Of patients	Percentage(%)
1	Naa	3	7.5%
2	Niram	-	-
3	Mozhi	-	-
4	Vizhi	-	-
5	Malam	22	55%
6	Moothiram	-	-
7	Naadi(thontha naadi)	40	100%
8	Sparisam	-	-



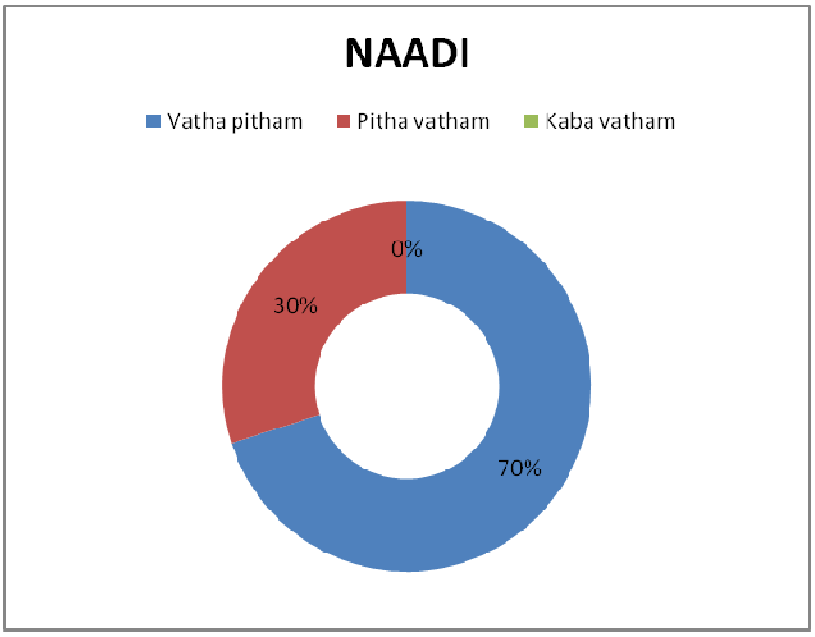
Inference

It was learnt during the study that thontha naadi was noted in all 40 cases, malam was affected in 55% of cases and naa in 7.5% of cases.

15. NAADI

Table 15. Illustrates the pulse reading (naadi)

S.no	Parameters	No. Of patients	Percentage(%)
1	Vatha pitham	28	70%
2	Pitha vatham	12	30%
3	Kaba vatham	-	-



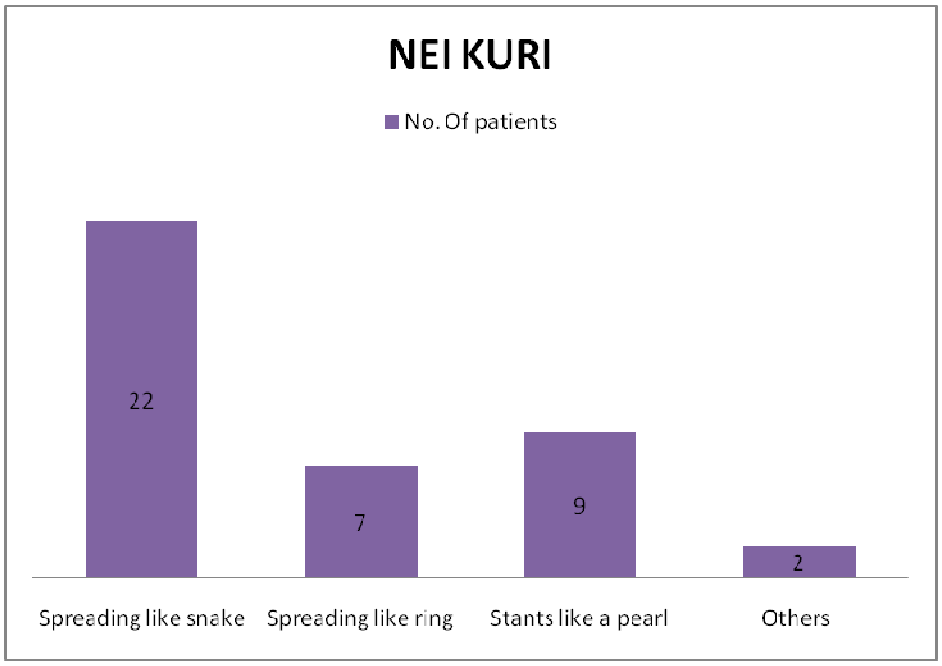
Inference

As mentioned above thontha naadi was noted in all cases and among them 70% were vatha pitha naadi and 30% were pitha vatha naadi .

16 NEIKURI

Table 16. Illustrates the neikuri analysis

S.no	Inference	No. Of patients	Percentage(%)
1	Spreading like snake	22	55%
2	Spreading like ring	7	17.5%
3	Stants like a pearl	9	22.5%
4	Others	2	5%
5	Total	40	100%

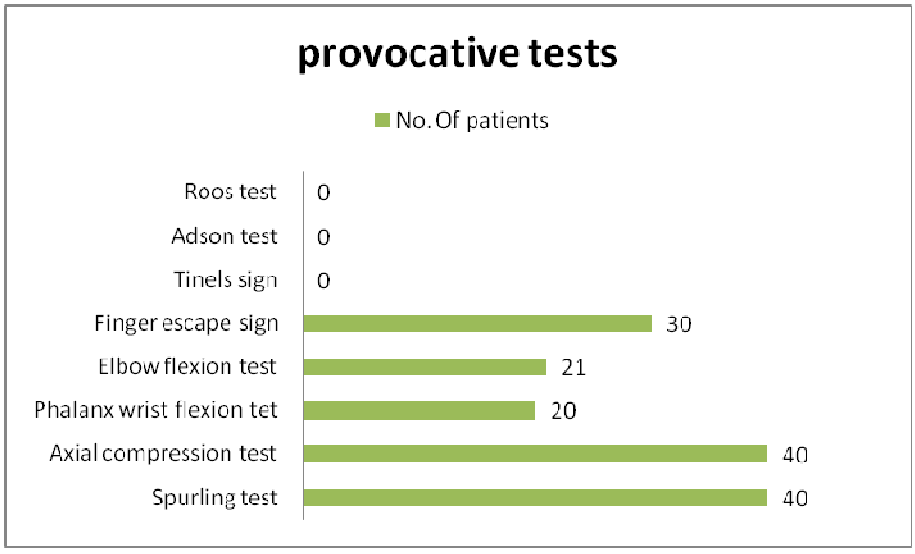


Inference

In neikuri analysis 55% of the cases presented with vatha neer, 22.5% with kaba neer, 17.5% with pitha neer, and the remaining 5% with other neer.

Table17. Provocative tests

S.no	Clinical features	No. Of patients	Percentage
1	Spurling test	40	100%
2	Axial compression test	40	100%
3	Phalanx wrist flexion tet	20	50%
4	Elbow flexion test	21	52.5%
5	Finger escape sign	30	75%
6	Tinels sign	-	-
7	Adson test	-	-
8	Roos test	-	-

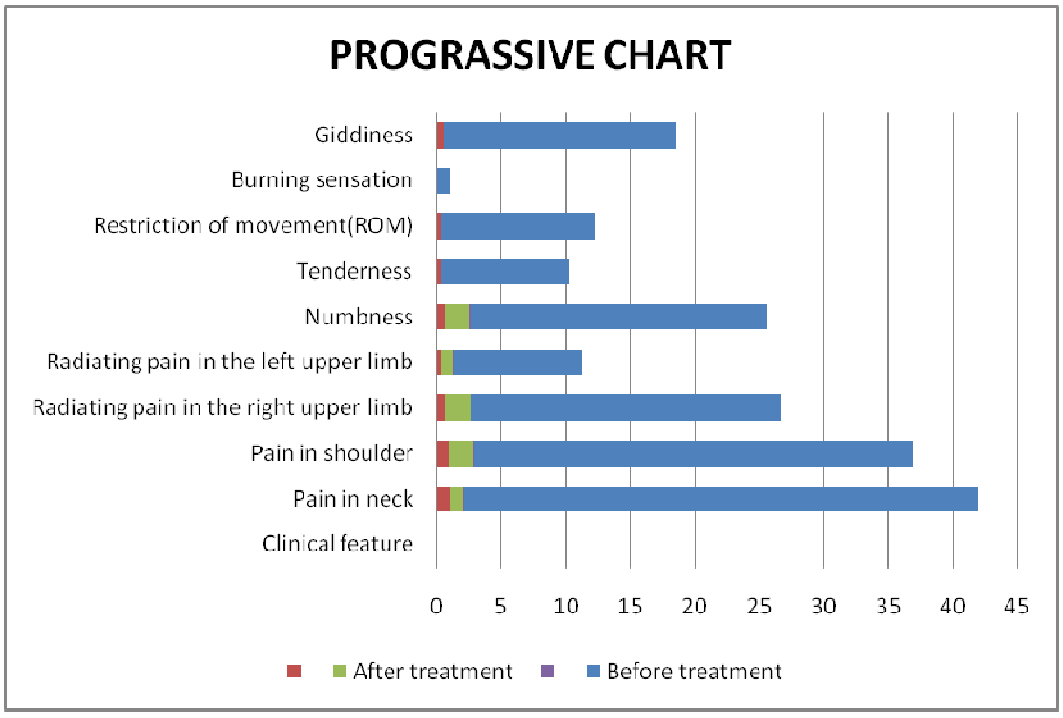


Inference

Based on modern aspect, for the diagnostic purpose and to determine the differential diagnosis few provocative tests were done and noted in all 40 cases spurling test, axial compression sign were positive in all cases (100%) and tinel's sign, adson's test. Roo's test were negative in all cases.

Table 18. Progressive chart

S.no	Clinical feature	Before treatment		After treatment	
		No.Of cases	Percentage	No.Of cases	percentage
1	Pain in neck	40	100%	1	2.5%
2	Pain in shoulder	34	85%	2	5%
3	Radiating pain in the right upper limb	24	60%	2	5%
4	Radiating pain in the left upper limb	10	25%	1	2.5%
5	Numbness	23	57.5%	2	5%
6	Tenderness	10	25%	0	-
7	Restriction of movement(ROM)	12	30%	0	-
8	Burning sensation	1	2.5%	0	-
9	Giddiness	18	45%	0	-

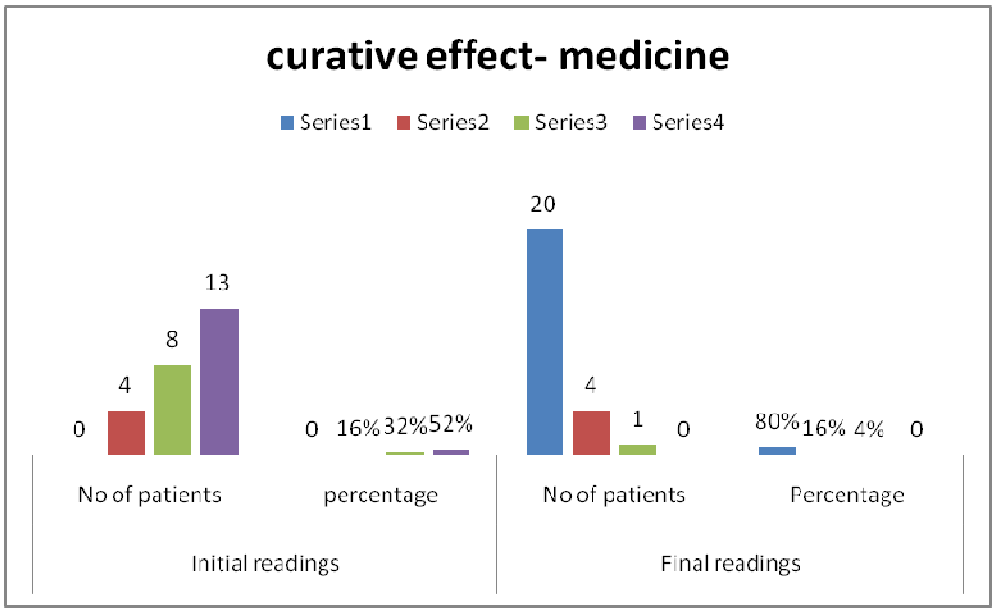


Inference

It was noted that, clinical manifestations like pain in the neck, restriction of movements and radiation of pain to other parts were remarkably reduced after treatment when compared to that of before treatment, Numbness and tenderness showed moderate reduction after treatment.

Table 19. Assessment of curative effects in patients treated only with trail drug (internal and external medicines)

Symptoms	Initial readings		Final readings	
	No of patients	percentage	No of patients	Percentage
No pain	0	-	20	80%
Mild	4	16%	4	16%
Moderate	8	32%	1	4%
Severe	13	52%	0	-

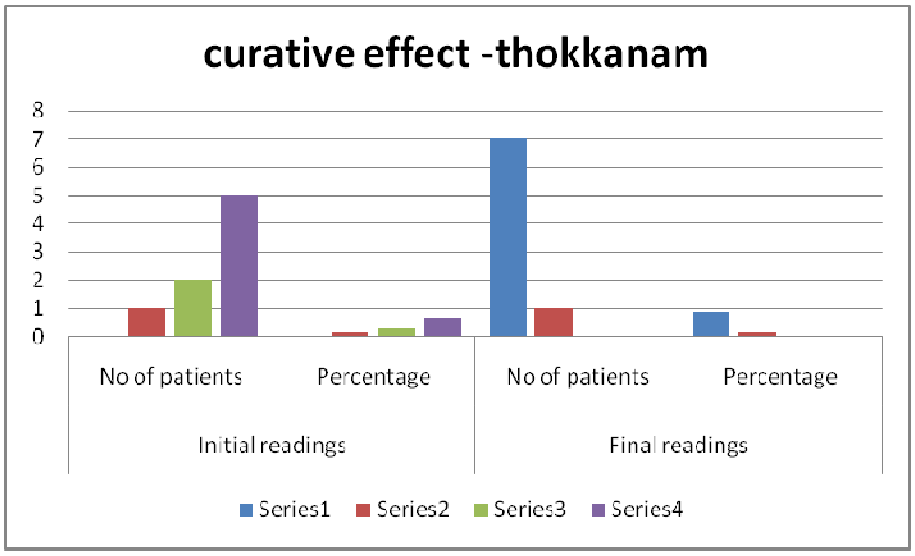


Inference

From the above study, it was inferred that severe pain that was noted in patients before treatment (52%) had a remarkable decline after treatment (80%), similarly moderate and mild pain were also observed to have decreased after treatment.

Table 20. Assessment of curative effects in cervical spondylosis patients treated with trail drugs along with complimentary therapy (Thokkanam)

Symptoms	Initial readings		Final readings	
	No of patients	Percentage	No of patients	Percentage
No pain	0	-	7	87.5%
Mild	1	12.5%	1	12.5%
Moderate	2	25%	0	-
Severe	5	62.5%	0	-

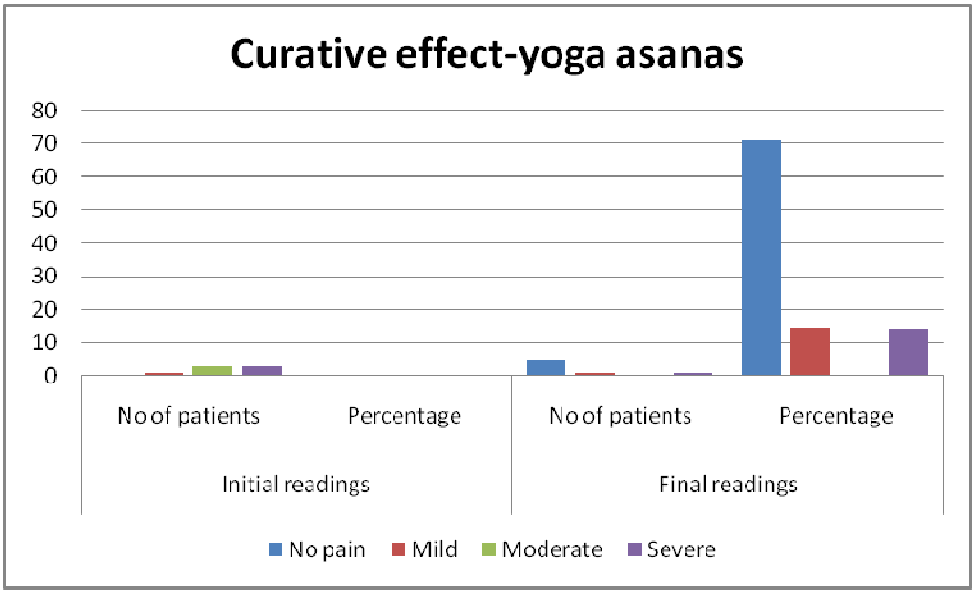


Inference

Administration of trial drug along with complementary therapy reduced severe pain in almost all the cases, pain reduced in mild and moderate cases.

Table 21. Assessment of curative effects in cervical spondylosis patients treated with trail drugs. Along with complementary therapy (Yoga asanas)

S.no	symptoms	Initial readings		Final readings	
		No of patients	Percentage	No of patients	Percentage
1	No pain	0	-	5	71.4
2	Mild	1	14.3	1	14.3
3	Moderate	3	42.8	0	-
4	Severe	3	42.8	1	14.3



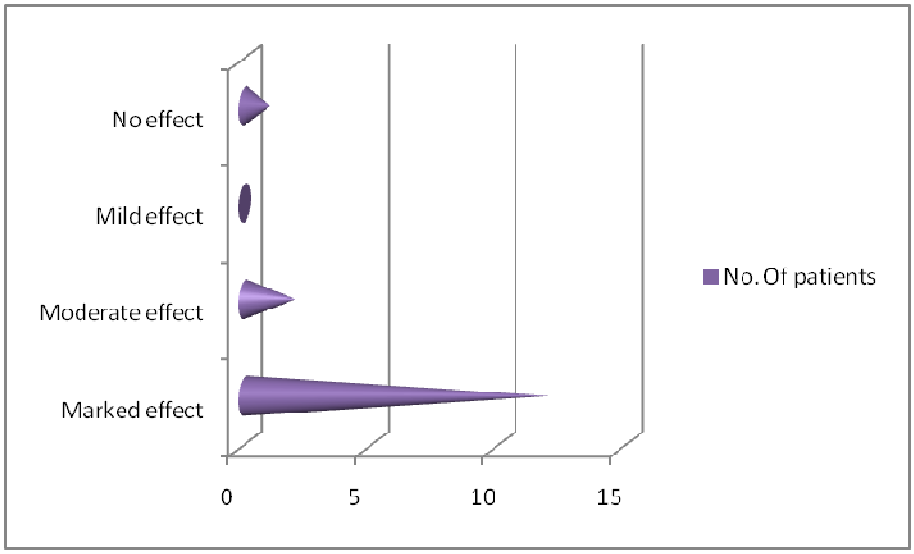
Inference

Administration of trial drug along with complementary therapy reduced severe pain in almost all the cases.

Table 22. Effect of trail drug along with complementary therapies

S.no	Effect of therapy	No. Of patients	Percentage(%)
1	Marked effect	12	80%
2	Moderate effect	2	13.3
3	Mild effect	0	-
4	No effect	1	6.6

Table 22. Effect of trail drug along with complementary therapies



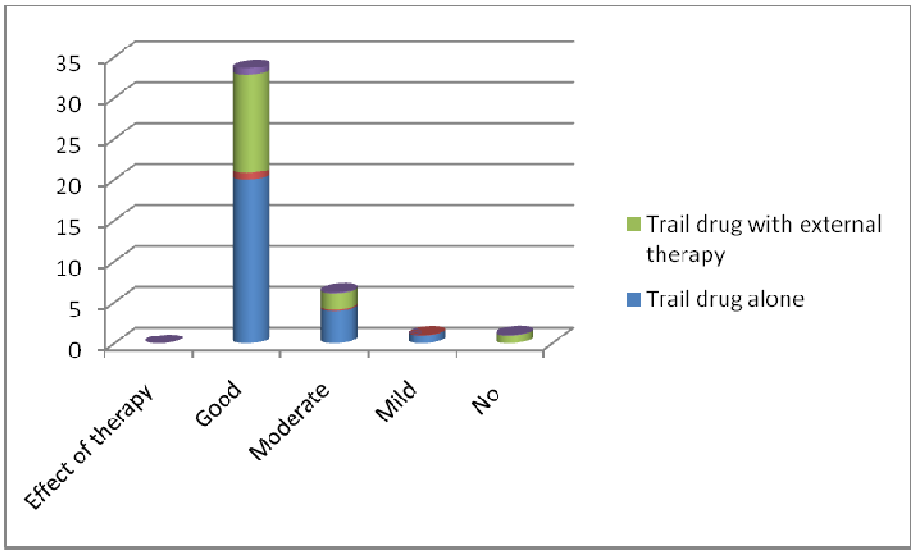
Inference

Administration of trial drug along with complementary therapies had a good response 80% moderate with 13.33% .

Table 23. Comparison between effective of trail drug and trail drug with complementary therapies

S.no	Effect of therapy	Trail drug alone		Trail drug with external therapy	
		No.Of cases	percentage	No.Of cases	Percentage
1	Good	20	80%	12	80%
2	Moderate	4	16%	2	13.3%
3	Mild	1	4%	0	-
4	No	0	-	1	6.6%

Table 23. Comparison between effective of trail drug and trail drug with complementary therapies



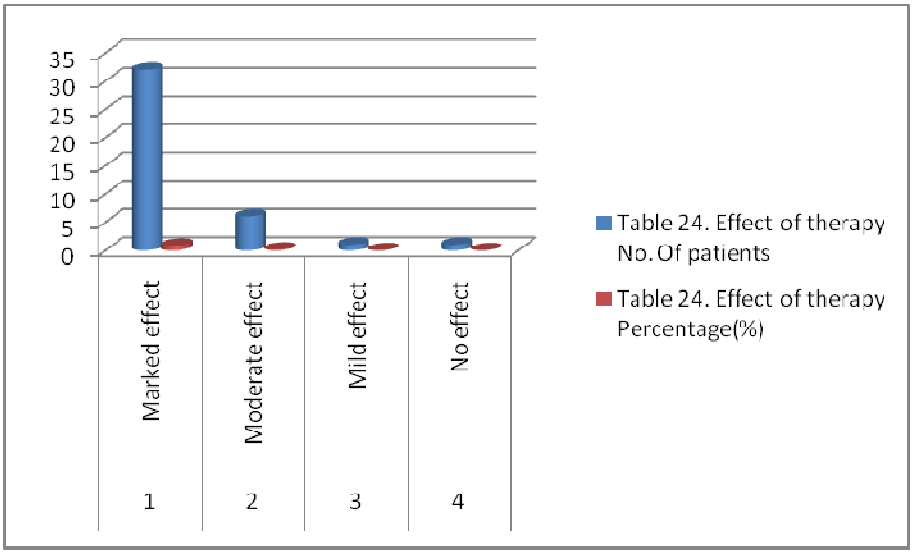
Inference

From the above data, it can be concluded that administration of trial drug along with complementary therapies had comparatively more effect than administering trial drug alone.

Table 24. Effect of therapy

S.no	Effect of therapy	No. Of patients	Percentage(%)
1	Marked effect	32	80%
2	Moderate effect	6	15%
3	Mild effect	1	2.5%
4	No effect	1	2.5%

Table 24. Effect of therapy



Inference

Thus from the analysis of the data collected during the course of treatment and at the end of treatment it is inferred that the overall effect of the therapy (Internal, external and complementary) had marked effect of 80% moderate effect of 20% and mild effect of 2.5% and 2.5% has no effect.

S:N0	IP:NO	NAME	AGE/SEX	DATE OF ADMISSION	DATE OF DISCHARGE	TREATED DAYS	EFFECT OF THERAPY
1.	63354	Aysha	53/F	25-06-2017	12-08-2017	48 Days	Marked
2.	63487	Chithambaravalli	50/F	25-06-2017	12-08-2017	48 Days	Marked
3.	64138	Ramachandran	58/M	27-07-2017	07-09-2017	35 Days	Mild
4.	109915	Kalyani	43/F	12-11-2017	23-01-2018	42 Days	Marked
5.	112931	Stephan	53/M	22-12-2017	07-02-2018	48 Days	Marked
6.	113035	Indiraganthi	52/F	22-12-2017	07-02-2018	48 Days	Marked
7.	1278	Marimuthu	33/M	04-01-2018	20-02-2018	48 Days	Marked
8.	1537	Muthukrishnan	57/M	04-01-2018	07-02-2018	35 Days	Mild
9.	6651	Subbu	53/F	19-01-2018	16-02-2018	28 Days	Moderate
10.	7755	Muthamilselvi	36/F	23-01-2018	12-03-2018	48 Days	Marked
11.	7962	Bhuvaneshwari	37/F	23-01-2018	12-03-2018	48 Days	Marked
12.	8276	Ganesan	38/M	24-01-2018	12-03-2018	48 Days	Marked
13.	9936	Thangaperumal	55/M	29-01-2018	05-03-2018	35 Days	Marked
14.	10079	Seethalaxshmi	47/F	01-02-2018	21-03-2018	48 Days	Marked
15.	11346	Lakshmi	58/F	02-02-2018	22-03-2018	48 Days	Mild
16.	12258	Nagarajan	49/M	05-02-2018	27-03-2018	48 Days	Marked
17.	12268	Jeya	40/F	05-02-2018	21-03-2018	42 Days	Marked
18.	12567	Nathina banu	38/F	06-02-2018	28-03-2018	48 Days	Marked
19.	28983	Pandaram	60/M	27-03-2018	24-04-2018	28 Days	Mild
20.	35315	Sudha	30/F	18-04-2018	05-06-2018	48 Days	Marked
21.	28633	Umamaheshwari	38/F	26-04-2018	08-05-2018	42 Days	Marked
22.	35447	Lakshmi	41/F	18-04-2018	05-06-2018	48 Days	Marked
23.	35450	Velu	53/M	18-04-2018	05-06-2018	48 Days	Mild
24.	74906	Selvi	45/F	18-04-2018	05-06-2018	48 Days	Marked
25.	75001	Thangam	52/F	19-04-2018	20-06-2018	48 Days	Marked

S:N0	IP:NO	NAME	AGE/SEX	DATE OF ADMISSION	DATE OF DISCHARGE	TREATED DAYS	EFFECT OF THERAPY
1.	2167	Pitchammal	60/F	01-08-2017	16-08-2017	16 Days	Marked
2.	3331	Esakiyammal	55/F	22-12-2017	06-01-2018	15 Days	Marked
3.	3361	Ramasamy	57/M	27-12-2017	13-02-2018	44 Days	Marked
4.	801	Kaliyapan	52/M	27-12-2017	15-01-2018	19 Days	Marked
5.	3369	Revathy	32/F	28-12-2017	19-01-2018	22 Days	Marked
6.	169	Valliyammal	48/F	24-01-2018	08-02-2018	16 Days	Marked
7.	170	Jamuna	58/F	24-01-2018	08-02-2018	16 Days	Mild
8.	676	Lakshmi	55/F	24-01-2018	12-03-2018	20 Days	Moderate
9.	487	Ponsanthi	40/F	30-01-2018	23-02-2018	25 Days	Marked
10.	330	Annathai	59/F	08-02-2018	23-02-2018	16 Days	Marked
11.	329	Gnanaiya	60/M	08-02-2018	17-02-2018	20 Days	Mild
12.	3279	Sembagavalli	47/F	14-02-2018	29-03-2018	43 Days	Marked
13.	484	Muthu	60/M	22-02-2018	01-03-2018	17 Days	No Effect
14.	771	Pushpam	49/F	20-03-2018	04-04-2018	15 Days	Marked
15.	1022	Somu	60/M	16-04-2018	20-05-2018	16 Days	Marked

BLOOD INVESTIGATION BEFORE AND AFTER TREATMENT – OP PATIENTS

S.NO	OP.NO	TC		DC										HB		ESR		BLOOD SUGAR				BLOOD UREA		SERUM CHOLESTEROL	
				N		L		E		B		M						F		PP					
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	63354	7800	7900	66	60	28	33	6	1					10.7	11.6	30	16	76	80			20	18	172	170
2.	63487	9000	9100	60	62	37	36	3	2					8.9	10.8	30	20	96	102			17	17	160	165
3.	64138	7200	7300	65	67	32	31	3	2					11.8	12	26	10	79	76			18	17	128	130
4.	109915	7400	8000	60	61	38	37	2	2					11	11.2	28	16	113	115			23	20	140	138
5.	112931	8800	9400	64	64	32	34	4	2					10.8	11.6	34	26	126	120			26	20	164	170
6.	113035	8900	9100	67	66	30	33	3	1					11	13	38	25	80	82			34	30	130	134
7.	1537	7500	8000	50	67	46	31	4	2					13	14	21	18	100	106			21	18	160	162
8.	1726	7600	8200	50	61	44	37	6	2					11	12.6	22	18	81	90			24	20	137	140
9.	6651	6600	7200	63	66	34	33	3	1					12.9	13	20	10	110	104			12	12	120	120
10.	7755	8000	8400	60	64	36	34	4	2					12.8	14	34	12	75	76			40	26	144	148
11.	7862	9400	9600	72	74	21	24	7	2					10.9	11.4	18	12	95	100			15	12	180	186
12.	8276	7600	8100	57	64	40	34	3	2					12	12	20	12	110	108			24	22	140	152
13.	9936	7400	7600	54	64	42	33	4	3					11.9	13	15	13	102	106			21	18	143	140
14.	10079	8800	9000	67	68	30	30	3	2					10.9	12	30	16	94	100			23	18	158	160
15.	11346	7600	8100	64	65	32	31	4	3					10	11.8	28	10	86	85			35	32	174	170
16.	12258	6400	7100	57	61	36	37	7	2					10. 4	12	20	12	116	110			19	14	197	200
17.	12268	9200	9500	67	66	28	32	5	2					11.4	12	15	10	103	100			15	12	187	190
18.	12567	5600	6400	53	67	42	32	5	2					10.2	11	25	16	98	110			34	20	186	178
19.	28633	8400	8500	63	64	35	34	2	1					8.6	10	34	18	98	104			17	15	160	166
20.	28983	7800	8100	65	65	31	32	4	3					9	9.8	40	32	78	86			34	28	180	190
21.	35315	7400	7800	65	66	31	33	4	1					11	11.5	32	18	110	108			31	30	200	210
22.	35447	9000	9100	65	66	32	32	3	2					9.6	10	42	36	94	90			36	34	146	146
23.	35450	8900	9100	62	64	36	35	2	1					7.5	8.5	41	37	100	108			18	16	150	150
24.	74906	7500	7400	67	67	30	31	3	2					11.8	12	32	24	96	90			20	20	163	160
25.	75002	9100	9400	64	64	32	34	4	2					9.6	11	40	30	102	100			30	20	178	172

BLOOD INVESTIGATION BEFORE AND AFTER TREATMENT – IP PATIENTS

S.NO	IP.NO	TC		DC										HB		ESR		BLOOD SUGAR				BLOOD		SERUM	
				N		L		E		B		M						F		PP		UREA		CHOLESTEROL	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	2167	9000	9100	60	62	37	36	3	2					7.8	8.6	24	20	96	104			20	18	147	150
2.	3279	8400	8500	65	66	32	32	3	2					9.8	10.8	28	16	70	76			18	18	165	165
3.	3331	8900	9100	66	68	32	31	2	1					10.8	11	42	17	79	78			24	22	160	162
4.	3361	7800	8100	64	65	32	32	4	3					7.4	8.4	38	25	89	90			21	20	150	154
5.	3369	8100	8700	62	65	34	33	4	2					12.5	12.6	42	26	113	118			23	22	152	150
6.	169	7600	7900	60	61	38	37	2	2					10.8	11.2	40	30	101	115			20	20	180	185
7.	170	9100	9400	67	67	32	31	4	2					10.6	12	26	18	92	100			36	34	162	165
8.	329	7400	7800	67	67	30	31	3	2					11	11.6	24	16	78	80			34	32	165	173
9.	330	7800	7900	63	64	35	35	2	1					11.2	12	42	40	110	120			18	18	146	150
10	484	8900	9000	60	64	38	34	2	2					10.2	10.4	38	30	116	118			22	20	158	156
11	487	7500	7900	60	62	37	36	3	2					12	12.6	25	18	101	115			20	18	160	167
12	676	9000	9100	67	66	30	33	3	1					12	13.2	48	36	80	86			34	32	180	182
13	771	8900	9000	60	61	38	37	2	2					9	11	24	13	92	98			17	17	165	166
14	801	9200	9400	63	67	35	32	2	1					9.8	10	32	24	120	118			20	20	130	132
15	1022	7500	7900	60	62	37	36	3	2					12	13.2	42	30	74	80			35	34	145	149

URINE EXAMINATION BEFORE & AFTER TREATMENT – IN PATIENTS

S.no	OP.no	Before treatment			After treatment		
		Albumin	Sugar	Deposit	Albumin	Sugar	Deposit
1.	63354	Nill	Nill	NAD	Nill	Nill	NAD
2.	63487	Nill	Nill	NAD	Nill	Nill	NAD
3.	64138	Nill	Nill	NAD	Nill	Nill	NAD
4.	109915	Nill	Nill	NAD	Nill	Nill	NAD
5.	112931	Nill	Nill	2-3 pus cells	Nill	Nill	1-2 Pus cell
6.	113035	Nill	Nill	NAD	Nill	Nill	NAD
7.	1537	Nill	Nill	NAD	Nill	Nill	NAD
8.	1726	Nill	Nill	NAD	Nill	Nill	NAD
9.	6651	Nill	Nill	NAD	Nill	Nill	NAD
10.	7755	Nill	Nill	NAD	Nill	Nill	NAD
11.	7862	Nill	Nill	NAD	Nill	Nill	NAD
12.	8276	Nill	Nill	1-2 pus cells	Nill	Nill	NAD
13.	9936	Nill	Nill	NAD	Nill	Nill	NAD
14.	10079	Nill	Nill	NAD	Nill	Nill	NAD
15.	11346	Nill	Nill	NAD	Nill	Nill	NAD
16.	12258	Nill	Nill	NAD	Nill	Nill	NAD
17.	12268	Nill	Nill	NAD	Nill	Nill	NAD
18.	12567	Nill	Nill	NAD	Nill	Nill	NAD
19.	28633	Nill	Nill	NAD	Nill	Nill	NAD
20.	28983	Nill	Nill	NAD	Nill	Nill	NAD
21.	35315	Nill	Nill	2-3 pus cell	Nill	Nill	1-2 Pus cells
22.	35447	Nill	Nill	NAD	Nill	Nill	NAD
23.	35450	Nill	Nill	NAD	Nill	Nill	NAD
24.	74906	Nill	Nill	NAD	Nill	Nill	NAD
25.	75002	Nill	Nill	NAD	Nill	Nill	NAD

URINE EXAMINATION BEFORE & AFTER TREATMENT – IN PATIENTS

S.no	Ip.no	Before treatment			After treatment		
		Albumin	Sugar	Deposit	Albumin	Sugar	Deposit
1	2167	Nill	Nill	NAD	Nill	Nill	NAD
2	3279	Nill	Nill	NAD	Nill	Nill	NAD
3	3331	Nill	Nill	NAD	Nill	Nill	NAD
4	3361	Nill	Nill	NAD	Nill	Nill	NAD
5	3369	Nill	Nill	NAD	Nill	Nill	NAD
6	169	Nill	Nill	NAD	Nill	Nill	NAD
7	170	Nill	Nill	NAD	Nill	Nill	NAD
8	329	Nill	Nill	2-3pus cell	Nill	Nill	1-2 pus cell
9	330	Nill	Nill	NAD	Nill	Nill	NAD
10	484	Nill	Nill	NAD	Nill	Nill	NAD
11	487	Nill	Nill	NAD	Nill	Nill	NAD
12	676	Nill	Nill	NAD	Nill	Nill	NAD
13	771	Nill	Nill	NAD	Nill	Nill	NAD
14	801	Nill	Nill	NAD	Nill	Nill	NAD
15	1022	Nill	Nill	NAD	Nill	Nill	NAD

DISCUSSION

Based on the clinical manifestations discussed in Yugi vaithiya chinthamani 800 forty cases were enrolled for the study. Envagaithervugal the siddha diagnostic method was used to diagnose the disease and it was confirmed with the modern investigations. After confirmation of the diagnosis the trial drug was administered along with the special therapies. Observations were noted and analysed. They are discussed here under.

Age distribution

The statistical study shows high incidence of Cegana vatham in the age group between 51-60 years as it is one of the degenerative disease and lowest incidence in the age between

20-30.

Most of the patients belong to pithakalam.

This information is bestowed by our siddhars as the wordings.

“வேண்டா ஐம்பதாம் வயதுதன்னில்

விரைந்துபிருதிவியில் அப்புமேவும் பாரே”.

The target sites affected in cervical spondylosis are generally bones, muscles, nerves, hairs, blood, urine, fat which are the components of appu and prithiviboothas (Appu+ prithivi = kabam responsible for destruction). Hence they begin to degenerate above fifty.

Sex distribution

There is a slight variation in the male, female ratio and it is noted obviously in the study.

Thinai

About 95% of patients from maruthanilam. It may be due to altered lifestyle, food habits etc.

Seasonal distribution

Most of the patients came during, Munpani kaalam, Pinpani kaalam, Elavenil kaalam.

Etiological factors

Majority of patients of the Ceganavatham was caused mainly (55%) due to the nature of occupation. the remaining were due to other factor like senility and exposure to cold..

Occupational status

The rate of incidence is higher in occupational group which includes home maker (35%) and Agricultural labour (15%) Beedi workers (20%), weight lifters (15%) Tailors(10%). homemakers are mostly affected.

Clinical Manifestations

Pain in the nape of the neck is present in all forty cases (100%), 85% of cases had radiating pain in upper limbs, 60% of cases had stiffness in the Neck. Hence symptoms associated very well with the disease as proved by the statistical tests.

Duration of illness

Most of the patient with the disease Cegana vatham reflected its symptoms over a period of 6-12 months which was confirmed during the history taking while 40% of the patients reported the data.

Derangement in vatha

Viyanan and Samanan was affected in all 40 cases (100%).

Disturbances in Pitha

Mostly Sathagapitham was affected in all 40 cases (100%).

Disturbances in Kabha

Almost Santhigam was affected in all 40 cases (100%).

Udal Thathukkal

In this study the patients was affected with seven thathus saram, senner, kozhuppu, enbu in 100% of cases, oon in 25% cases was affected.

Envagai Thervugal

In this study thontha naadi was noted in all 40 cases, malam was affected in 55% of cases and naa in 7.5% of cases.

In naadi 70% were vatha pitha naadi, 30% were pitha vatha naadi and remaining were kabavatha naadi.

Investigation

Laboratory investigations were done in all the cases before and after treatment. The significant variations occur in parameters like ESR and HB, while other parameters have insignificant variation.

Pre clinical studies

The phytochemical study of "Vathathirku leghiyam" had revealed the presence of calcium, ferrous iron, tannic acid, unsaturated compound, reducing sugar.

Pharmacological studies

The pharmacological studies done in "Vathathirku leghiyam" revealed the presence of actions such as

1. Anti – inflammatory action
2. Analgesic activity.

Toxicity studies

Acute toxicity studies in rats for "Vathathirku leghiyam" revealed that it has no toxicity effect.

Treatment

The treatment was aimed to retain the deranged thoshas and providing relief from symptoms. Before treatment the patients were advised to take vellai ennai 15ml with hot water during morning for first day of treatment.

From the second day onwards Internal medicine Vathathirku leghiyam 6.02gm two times a day after food and Pancharka thylam is given as external.

At the time of treatment the patients were advised to follow pathiyam and specifically advised to avoid foods which increase vadha.

Along with the course of treatment the complementary therapies like Thokkanam and Yoga asanas therapy were given additionally to some of the patients.

The outcome of this study is mainly assessed by reduction in pain in cervical joint. Increased range of reduction of restricted movements and improvement in quality of life universal pain assessment scale was also used to detect proper outcome. No adverse effect was noted for both internal and external medicine along with the course of treatment.

SUMMARY

40 cases with Cegana vatham were diagnosed clinically based on yugi 800 and admitted in the inpatient ward and outpatient ward of post graduate department of sirappu maruthuvam, Government Siddha Medical College Hospital, palayamkottai and treated by the trial medicines.

- Laboratory diagnosis of Ceganavatham was done by siddha diagnostic principles and endorsed by modern methods of investigations.
- The various siddha aspects of examination of the disease were carried out and were recorded in the proforma.
- The trial medicine chosen for both internal and external treatments were Vathathirku leghiyam 6.02gms/days in two doses for forty eight days as per the severity of the diseases, Pancharka thylam (External)
- Before starting the treatment careful detailed history was carried out and recorded for the forty selected cases.
- During the period of treatment all the patients were put under pathiyam (A specific dietary regimen)
- A periodical laboratory investigation was made for all the cases along with the radiological investigations.
- The observations made during the clinical study shows that the main internal drug Vathathirku leghiyam is clinically effective.
- Though there was appreciable clinical improvement, there was not much remarkable radiographic changes.

  The action of external application Pancharka thylam with Thokkanam and Yoga asanas is also quite remarkable.

CONCLUSION

All 40 patients (25 OPD and 15 IP – 8 patients with trial medicines and Massage, 7 with Yoga asanas along with trial medicines). were treated for this dissertation work with Vathathirku leghiyam 6.02gm/day in two doses a day and Pancharka thylam (externally)

In the pre clinical study pharmacological evaluation of the trial drug shows.

- Significant analgesic effect
- Significant Anti inflammatory effect (Internal medicine)

In the preclinical study toxicity study of "Vathathirku leghiyam" shows that the trial drug had no acute toxicity.

The overall effects of the clinical trial drug are

Marked effect	-	80%
Moderate effect	-	13%
Mild effect	-	0%
No effect	-	6.6%

This result of the clinical trial illustrates the marked effect of the drugs and complementary therapy.

The trial drug "Vathathirku leghiyam" and external "Pancharka thylam" is effective. No adverse effects were noticed during the treatment period. So the trial medicine is safe and easily preparable medicine.

INGREDIENTS OF VATHATHIRKKU LEGHIYAM

Sathikai

Kirambu

Omam

Milagu

Inji

Seeragam

Elam

Poondu

Milk

Nilapanai Kizhangu

Sathipathiri

Thippili

INGREDIENTS OF PANCHARKA THYLAM

Veliparuthi

Athandai

Mookirattai

Thagarai vithai

Kostam

Amukkara

Erukku charu

Nochi

Indhuppu

Kasthuri Manjal

Gingelly Oil

Charanai ver

VATHATHIRKKU LEGHIYAM

PANCHARKA THYLAM

TREATMENT

TRIAL DRUGS:

INTERNAL DRUG: VATHATHIRKKU LEGHIYAM

REFERANCE: ATHMARATCHAMIRTHAM

INGREDIENTS:

Poondu (Allium sativum)	-	1 Padi (1440ml)
Sathikai (Myristica fragrans)	-	5 varagan (21gm)
Sathipaththiri (Myristica fragrans)	-	5 varagan (21gm)
Kirambu (Syzygium aromaticum)	-	5 varagan(21gm)
Seeragam (Cuminum cyminum)	-	5 varagan (21gm)
Elam (Elettaria cardamomum)	-	5 varagan(21gm)
Akkarakaram (Anacylus pyrethrum)	-	5 varagan(21gm)
Thippilli moolam (Piper longum)	-	5 varagan(21gm)
Chukku (Zingiber officinale)	-	5 vargan(21gm)
Milagu (Piper nigrum)	-	5 varagan(21gm)
Thippili (Piper longum)	-	5 varagan(21gm)
Omam (Trachyspermum ammi)	-	5 varagan(21gm)
Parangipattai (Smilax china)	-	5 varagan(21gm)
Nilapanaikizhangu (Curculigo orchioides)	-	5 varagan(21gm)
Cow milk	-	1 Padi(1440ml)
Nei (Ghee)	-	1 Padi(1440ml)
Then(honey)	-	1 Padi(1440ml)

Dose : Kottaipakalavu (6.022)

Duration : 48 Days

EXTERNAL DRUG: PANCHARKA THYLAM

REFERANCE: Agathiyar mani ennum vaithiya sinthamani venba-4000

INGREDIENTS:

Erukku (Calotropis gigantea)	-	5palam(175gm)
Notchi (Vitex negundo)	-	5palam(175gm)
Charanai (Trianthema portulacastrum)	-	5palam(175gm)
Athandai (Capparis zeylanica)	-	5palam(175gm)
Amukkura (Moringa oleifera)	-	5palam(175gm)
Murungai (Moringa oleifera)	-	5palam(175gm)
Veliparuthi (Pergularia daemia)	-	5palam(175gm)
Mukkirattai (Boerhaavia diffusa)	-	5palam(175gm)
Thaneer (Water)	-	1 naazhi(1.34lt)
Induppu (Sodium chloride impure)	-	1palam(35gm)
Thagaraivithai (Cassia tora)	-	1palam(35gm)
Chukku	-	1palam(35gm)
Elam	-	1palam(35gm)
Kirambu (Syzygium aromaticum)	-	1palam(35gm)
kottam (Costus speciosus)	-	1palam(35gm)
Katturi manjal (Curcuma aromatic)	-	1 palam(35gm)
Gingelly oil (Sesamum indicum)	-	4 padi(5.36litre)
Goat”s milk	-	4 padi(5.36 litre)

1. பூண்டு :

Botanical Name	:	Allium sativum
Synonyms	:	லசுனம், காயம், வெள்ளுள்ளி, வெள்ளை பூண்டு.
Family	:	Liliaceae
Part used	:	Bulb
சுவை	:	கார்ப்பு
வீரியம்	:	வெப்பம்
பிரிவு	:	கார்ப்பு,
Therapeutic action	:	உரமாக்கி, அகட்டுவாய்வகற்றி, உடற்றேற்றி, கோழையகற்றி.
Chemical constituents	:	Allin, ajoeje, vinyldithins, vitamin,protein, saponin, phytoalexin, minerals.

பொதுகுணம் :

” சன்னியொடு வாதந் தலை நோவு தாள்வலி
மன்னிவரு நீர்க்கோவை வன்சீதம் அன்னமே !
உள்ளிள்ளி கண்பாய் உளைமூல ரோகமும் போம்
வெள்ளுள்ளி தன்னால் வெருண்டு ” !

2. சாதிக்காய் :

Botanical Name	:	Myristica fragrans
Synonyms	:	குலக்காய்
Family	:	Myristicaceae
Part used	:	Seed
சுவை	:	துவர்ப்பு, கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Therapeutic action	:	அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி, உரமாக்கி,
Chemical constituents	:	Myristicin, sabinene, allylbenzene, propyllbenzene.

பொதுகுணம் :

” தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்
ஓதுசுவா சங்காசம் உட்கிரணி - வேதோ
டிலக்காய் வரும்பிணிபோம் ஏற்ற மயல் பித்தங்
குலக்கா யருந்துவர்க்குக் கூறு ”.

3. சாதிபத்திரி

Botanical Name : Myristica fragrans

Family : Myristicaceae

Synonyms : ஜாதிப்பத்திரி, வசுவாசி

Part used : Aril

சுவை : கார்ப்பு, துவர்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic action : அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி, உறக்கமுண்டாக்கி

Chemical constituents : Myristicin, sabinene, allylbenzene, propyllbenzene.

பொதுகுணம் :

சாதிதரும் பத்திரிக்குத் தாபச் சுரந்தணியும்
ஓதுகின்ற பித்தம் உயருங்கான் - தாதுவிருத்தி
யுண்டாங் கிரகணியோ டோதக் கழிச்சலறும்
பண்டாங் குறையே பகர்.

(அ.கு)

4. கிராம்பு :

Botanical Name : Syzygium aromaticum

Family : Myrtaceae

Part used : Flower bud

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : அகட்டுவாய்வகற்றி, பசித்தீதூண்டி.

Chemical constituents : Eugenol, eugenitin, eugenin, kaempferol.

பொதுகுணம் :

" பித்த மயக்கம் பேதியோடு வாந்தியூம்போம்
சுத்திவிரத் தகடுப்புச் தோன்றுமோ " .

- அகத்தியர் குணவாகடம்

5. சீரகம்

Botanical Name	:	Cuminum cyminum
Synonyms	:	அசை, சீரி, உபகும்பபீசம், நற்சீரி, துத்தசாம்பலம், பிரத்தி-விகா, பித்தநாசினி, போசனகுடோரி, மேத்தியம்.
Family	:	Apiaceae
Part used	:	Fruit
சுவை	:	கார்ப்பு, இனிப்பு
வீரியம்	:	தட்பம்
பிரிவு	:	இனிப்பு
Therapeutic action	:	அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி, பசித்தீதூண்டி, துவர்ப்பி
Chemical constituents :		Limonene, 1,8 cineole, linalool, linalyl acetate.

பொதுகுணம் :

பித்தமெனு மந்திரியைப் பின்னப் படுத்தியவன்
சத்துருவை யுந்துறந்து சாதித்து - மத்தனெனும்
ராசனையு மீவென்று நண்பைப் பலப்படுத்தி
போசனகு டாரிசெயும் போர்.

(தேரன் வெண்பா)

6.ஏலம் :

Botanical Name	:	Elettaria cardamomum
Synonyms	:	ஆஞ்சி, கோரங்கம், துடி
Family	:	Zingiberaceae
Part used	:	Seed
சுவை	:	கார்ப்பு
வீரியம்	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Therapeutic actions	:	வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.
Chemical constituents	:	Limonene terpinolene alpha terpinyl acetate, Myrcene, Protocatechuic acid, 1,8 cineole.

பொதுகுணம் :

மலவாத மோடு வயிற்றுக் கொதிப்பு
சலமூறல் வாயினிப்பு தாகம் - சலபேதி
வேர்க்குந் தலைநோய் மிகுரூட்சை ஐயமிவை
போக்கு ஞ்சிற் றேலம் புகல்
ஏலத்தினால் வாதம் குணமாகும்.

(அ.கு)

7. அக்கரகாரம்

Botanical Name	:	Anacyclus pyrethrum
Synonyms	:	அக்கராகாரம் , அக்கிராகாரம்.
Family	:	Asteraceae
Part used	:	Rhizome
சுவை	:	கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic action : வெப்பமுண்டாக்கி, உமிழ்நீர்ப்பெருக்கி,

Chemical constituents : Pyrethrin

பொதுகுணம் :

அக்கர காரம் அதன்பேர் உரைத்தக்கால்
உக்கிரகால் அத்தோடம் ஓடுங்காண் - முக்கியமாய்க்
கொண்டால் சலம்ஊறும் கொம்பனையே ! தாகசுரம்
கண்டால் பயந்தோடுங் காண்.

(அ.கு)

- அக்கரகாரத்தால், பயங்கரமான காலின்குற்றம் (வாததோடம்) போகும்.

8.திப்பிலி மூலம் :

Botanical Name : Piper longum

Synonyms : அம்பினடி, கிரந்திவோர், கிரந்திகம்,தன்மன், தன்மூலம், திப்பிலிகட்டை, நறுக்குவோர், மோடிவோர்.

Family : Piperaceae

Part used : Root

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic action : பசித்தீத்தூண்டி

Chemical constituents : Coumaperine, piperolactam, demethoxycurcumin, aphanamol, piperidine.

9. சுக்கு :

Name	:	Zingiber officinale
Synonyms	:	அருக்கன், சுண்டி, சொண்டி, நவசுறு,நாகரம், சௌவர்ணம், விடமுடிய அமிர்தம், கடுபத்திரம்
Family	:	Zingiberaceae
Part used	:	Rhizome
சுவை	:	கார்ப்பு
வீரியம்	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Therapeutic actions	:	வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.
Chemical constituents	:	Isovanillin, Glycol monopalimitate, b- gingino, Beta - sitosterol palmitate, adenine, malemide 5 - oxime.

பொதுகுணம் :

வாதப் பிணிவயி றூதற் செவிவாய்
வலிதலை வலிகுலை வலியிரு விழிநீர்
சீதத் தொடுவரி பேதிப் பலரோ
சிகமலி முகமக முகமிடி கபமார்
சீதச் சரம்விரி பேதச் சுரநோய்
தெறிபடுமெனமொழி குவர்புவி தனிலே
ஈதுக் குதவுமி தீதுக் குதவா
தெனும்விதி யிலைநவ சுறுகுண முனவே.

(தே.கு)

- சுக்கினால் வாத பிணி தீரும்.

10. மிளகு :

Botanical Name	:	Piper Nigrum
Synonyms	:	கலினை, கோளகம், திரங்கள், சருமபந்தம், வள்ளிசம், மாசம்.
Family	:	Piperaceae
Part used	:	விதை
சுவை	:	கைப்பு, கார்ப்பு
வீரியம்	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Therapeutic actions	:	வாதமடக்கி, வீக்கங்கரைச்சி, நச்சரி, முறைவெப்பகற்றி.
Chemical constituents	:	Piperine, Superoxide anions, Nitric oxide. Dipiperamides D & E, Piptigrine, Wisanine.

பொதுகுணம் :

அளவையுறாக்காரம் அடைந்திருக்கும் வாத
விளைவையெல் லாமறுக்கும் மெய்யே - மிளகின்காய்
கண்டவர்க்கும் இன்பமாம் காரிகையே ! சீழ்மூலங்
கொண்டவர்க்கு நன்மருந்தாங் கூறு.

(அ.கு)

- மிளகு வாத விளைவுகள் எல்லாம் போக்கும்.

11. திப்பிலி :

Botanical Name	:	Piper longum
Synonyms	:	ஆர்கதி, உண்சரம், உலவைநாசி, காமன்குடாரி, சரம்,சாடி, துளவி, கணம், கலினி, அம்பு, ஆதிமருந்து.
Family	:	Piperaceae

Part used	:	Fruit
சுவை	:	இனிப்பு
வீரியம்	:	தட்பம்
பிரிவு	:	இனிப்பு
Therapeutic actions	:	வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி.
Chemical constituents	:	Coumaperine, piperolactam, demethoxycurcumin, aphanamol, piperidine.

பொதுகுணம் :

இருமல் குன்மம் இரைப்பு கயப்பிணி
ஈளை பாண்டு சந்யாசம் அரோசகம்
பொருமல் ஊதை சிரப்பிணி மூர்ச்சைநோய்
பூரிக் குஞ்சல தோடம் பீலிகமும்
வரும லப்பெருக் கோடு மகோதரம்
பெருமாலைப்புரி மேகப் பிடகமும்
பேருந் திப்பிலிப் பேரங்குரைக்கவே.

- திப்பிலி வாதம் தீர்க்கும்.

12. ஓமம்

Botanical Name	:	Trachyspermum ammi
Synonyms	:	அசம்தாகம், அசம்தா ஓமம்
Family	:	Apiaceae
Part used	:	Seed
Therapeutic action	:	பசித்தீத்தூண்டி, அகட்டுவாய்வகற்றி
Chemical constituents	:	Thymol, p-cymene

13. பறங்கிப்பட்டை

Botanical Name	:	Smilax china
Synonyms	:	மதுஸ்மிகம், மதுஸ்மீகி, சீனப்பட்டை, பறங்கிச்சக்கை
Family	:	Liliaceae
Part used	:	Root
சுவை	:	இனிப்பு
வீரியம்	:	தட்பம்
பிரிவு	:	இனிப்பு
Therapeutic action	:	உடற்றேற்றி, மேகப்பிணிவிலக்கி, காமம்பெருக்கி, தூய்மையாக்கி
Chemical constituents	:	Carotene, cryptoxanthin, neo-b-carotene

பொதுகுணம் :

தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை
மேகங் கடிகிரந்தி வீழ்மூலந் - தேகமுடன்
குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்
பட்டையினை யுச்சரித்துப் பார்.

(தே.கு)

- பறங்கிப்பட்டை பல வாதங்களையும் போக்கும்.

14. நிலப்பனைகிழங்கு

Botanical Name	:	Curculigo orchioides
Synonyms	:	வாராகி, தாலமூலி, திரளாரம், திரகத்தாரு திரணராசன் சகியம், தலைத்தாது, நிலவிழுமி, நேயம், குறத்தி, சசியம், சித்தி.

Family : Hypoxidaceae

Part used : Rhizome

சுவை : இனிப்பு

வீரியம் : தட்பம்

பிரிவு : இனிப்பு

Therapeutic action : உரமாக்கி, அகட்டுவாய்வகற்றி, துவர்ப்பி, சிறுநீர் பெருக்கி, வறட்சியகற்றி

Chemical constituents : Phenyl glycosides, orcinal glycoside, corchioside A

பொதுகுணம் :

மேக வனல்தணியும் வெண்குட்டந் தான்விலகும்
போக மிகவுமுறும் பொற்கொடியே ! - போகாத
சூலைமே கங்களோடு துன்னுகரும் புள்ளியும்போஞ்
சால நிலப்பனைக்குத் தான்.

15. பால்

Synonyms : பயம், கீரம், சுதை, பயசு, பாகு, அமுது, துத்தம், சாறு.

பொதுகுணம் :

"பாலர் கிழவர் பழஞ்சுரத்தோர் புண்ணாளி
சூலையர் மேகத்தோர் துர்பலத்தோர் ஏலுமிவர்
எல்லார்க்கு மாகும் இளைத்தவர்க்குஞ் சாதகமாய்
நல்லாய் பசுவின்பால் நாட்டு".

16. நெய்:

English Name: Ghee

பொதுக்குணம்:.

தாகமுழ லைகட்கம் வாந்தி பித்தம் வாயுபிர
மேகம் வயிற்றெரிவு விக்கலழல்-மாகாசங்
குன்மம் வறட்சி குடற்புரட்ட லஸ்திகட்கஞ்
சொன்மூலம் போக்கநிறைத் துப்பு.

17. தேன்:

பொதுக்குணம்:

ஆயுளுட னுட்டிணம ரோசி யகக்கபமு
மேய வழகம் வளர்த்திடுங்காண்-தூய
மதிய மெனுவதன மாதரசே நாளும்
புதிய நறுந்தேனாற் புகல்.

சுவை: இனிப்பு

செய்கை: உள்ளாழற்றி, மலமிளக்கி, துவர்ப்பி, அழகலகற்றி, கோழையகற்றி, பசித்தீத்தூண்டி, உரமாக்கி, தூக்கமுண்டாக்கி.

EXTERNAL DRUG – PANCHARKA THYLAM

1. எருக்கு :

Botanical Name : Calotropis gigantea

Family : Asclepiadaceae

Part used : Leaf

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Anti inflammatory, Analgesic.

Chemical constituents : Caoutchouc, asclepin, gigastin, mudarine.

பொதுகுணம் :

” வலிசூலை, வாயுவிட மந்தம் - மலபந்தம்
எல்லா மகலு, மெருக்கிலையைக் கண்டால் ”.

- அகத்தியர் குணவாகடம்

2. நொச்சி :

Botanical Name : Vitex negundo

Family : Verbenaceae

Part used : Leaf

சுவை : கைப்பு, கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Vermifuge, Alterative

Chemical constituents : Vitegnoside, 7,8 dimethyl herbacetin.

பொதுகுணம் :

..... கரநொச்சிற் பட்டையது

துள்ளு சன்னி வாதமகற்றும் .....

- அகத்தியர் குணவாகடம்

3. சாரணை :

Botanical Name : Trianthema portulacastrum

Family : Aizoaceae

Part used : Root

சுவை : கைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Chemical constituents : Trianthenol, 3-acetylaluritolic acid, p-methoxybenzoic acid.

4. ஆதண்டை :

Botanical Name: Capparis zeylanica

Family : Capparaceae

Part used : Root

சுவை : சிறுகைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Sedative, Stomachic

Chemical constituents: alpha & beta amyrin, n-tricontane

பொதுகுணம் :

" ..... வாத கடுப்பகலு மாதே ஆ தொண்டைக்குப்

போதப் பலபிணி போம்..... "

-அகத்தியர் குணவாகடம்

5. அசுவகந்தி :

Botanical Name : Withania somnifera

Family : Solanaceae

Part used : Rhizome

சுவை : கைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Sedative, Tonic, Deobstruent

Chemical constituents : Isopelletierine, anaferine, saponins, sitoindosides

பொதுகுணம் :

" கொஞ்ந் துவர்ப்பாங் கொடியகயம் சூலையரி

மிஞ்சுகரப் பான்பாண்டு வெட்பதட்பு - விஞ்சி "

- அகத்தியர் குணவாகடம்

6. முருங்கை :

Botanical Name : Moringa oleifera

Family : Moringaceae

Part used : Bark

சுவை : கைப்பு, துவர்ப்பு, இனிப்பு.

வீரியம் : தட்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Antispasmodic, Stimulant, Diuretic

Chemical constituents : Hexacosane, Flavanoids, Quercetin

பொதுகுணம் :

சிக்குருக்கு யப்பிஞ்சத் திச்சுரத்திற் குஞ்சநிக்கும்
அக்குருக்கு ரப்பம் அரோசிகட்குஞ் - சுக்கிலத்தின்
கொச்சை யுறவருந்திக் கூறுவதற்கு மாமதனைப்
பச்சை யுறவருந்திப் பார் " .

- தேரையர் குணவாகடம்

7. வேலிப்பருத்தி :

Botanical Name : Pergularia daemia

Family : Asclepiadaceae

Part used : Leaf

சுவை : கைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Anthelmintic, Emetic, Expectorant

Chemical constituents : Terpenoids, alpha-amyrin, beta-sitosterol

பொதுகுணம் :

" ..... கண்டிக்கும் வாதங் கடுஞ்சன்னி தோடமும்போம்
உண்டிக்கும் வாசனையாம் ஓது ".

- அகத்தியர் குணவாகடம்

8. மூக்கிரட்டை :

Botanical Name : Boerhaevia diffusa

Family : Nyctaginaceae

Part used : Leaf

சுவை : கைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Refrigerant, Laxative, Diuretic

Chemical constituents : Beta-sitosterol, Beta- D- glucose

பொதுகுணம் :

" மூக்கிரட்டையிவிலை முறையுண வாதநோ
யாக்கையிற் பெட்டி யரவென் வடங்குமே " .

- தேரன் வெண்பா

9. இந்துப்பு :

Chemical Name : Sodium chloride impure

சுவை : உவர்ப்பு

Therapeutic actions : Carminative, Stimulant, Laxative

Chemical constituents : Berberine

பொதுகுணம் :

அட்டகுன்ம மந்தம் அசிர்கரஞ்சூர சீதபித்தம்
துட்ட வையம் நாடிப்புண் தோடங்கள் - கெட்டமலம்
கட்டுவிட விந்தையக் காமியநோய்
வன்கரப்பான் விட்டு விட விந்துப்பை விள் ".

10. தகரை விதை :

Botanical Name : Cassia tora

Family : Fabaceae

Part used : Seeds

சுவை : கைப்பு, உவர்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Febrifuge, Laxative

Chemical constituents : Anthroquinones, Glycosides

பொதுகுணம் :

”வண்டு கடியுடனே வன்கடுவ னும்பலவாம்
பண்டு நமைப்புடையும் பண்டிதர்கள் - கண்டரைக்காய்
பித்த அனலும் பெருத்த தகரைவிதைக்
கித்தரையுள் நில்லா திசை ” .

- அகத்தியர் குணவாகடம்

11. சுக்கு :

Name : Zingiber officinale

Synonyms : அருக்கன், சுண்டி, சொண்டி, நவசுறு,நாகரம்,
சௌவர்ணம், விடமுடிய அமிர்தம், கடுபத்திரம்

Family : Zingiberaceae

Part used : Rhizome

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.

Chemical constituents : Isovanillin, Glycol monopalimitate, b- gingino, Beta - sitosterol palmitate, adenine, malemide 5 - oxime.

பொதுகுணம் :

வாதப் பிணிவயி றூதற் செவிவாய்

வலிதலை வலிகுலை வலியிரு விழிநீர்

சீதத் தொடுவரி பேதிப் பலரோ

சிகமலி முகமக முகமிடி கபமார்

சீதச் சரம்விரி பேதச் சுரநோய்

தெறிபடுமெனமொழி குவர்புவி தனிலே

ஈதுக் குதவுமி தீதுக் குதவா

தெனும்விதி யிலைநவ சுறுகுண முனவே.

(தே.கு)

12.ஏலம் :

Botanical Name : Elettaria cardamomum

Synonyms : ஆஞ்சி, கோரங்கம், துடி

Family : Zingiberaceae

Part used : Seed

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : வெப்பமுண்டாக்கி, அகட்டுவாய்வகற்றி, பசித்தீத்தூண்டி.

Chemical constituents : Limonene terpinolene alpha terpinyl acetate,

Myrcene, Protocatechuic acid, 1,8 cineole.

பொதுகுணம் :

மலவாத மோடு வயிற்றுக் கொதிப்பு

சலமூறல் வாயினிப்பு தாகம் - சலபேதி

வேர்க்குந் தலைநோய் மிகுரூட்சை ஐயமிவை

போக்கு ஞ்சிற் றேலம் புகல்

ஏலத்தினால் வாதம் குணமாகும். (அ.கு)

13. கிராம்பு :

Botanical Name : Syzygium aromaticum

Family : Myrtaceae

Part used : Flower bud

சுவை : கார்ப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Anti-spasmodic, Carminative, Stomachi

Chemical constituents : Essential oil mainly contain eugenol & eugenol acetate, beta-caryophyllene

பொதுகுணம் :

" பித்த மயக்கம் பேதியோடு வாந்தியும்போம்
சுத்திவிரத் தகடுப்புச் தோன்றுமோ " .

- அகத்தியர் குணவாகடம்

14. கோட்டம் :

Botanical Name : Costus speciosus

Family : Costaceae

Part used : Root

சுவை : கைப்பு, விறுவிறுப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Tonic, Stimulant, Diaphoretic

Chemical constituents : Tetracosanoic acid, succinicacid, beta sitosterol

பொதுகுணம் :

" நாட்டிலுறு வெட்டை நடுக்கம் எனுநோய்கள்
கோட்டமெனச் சொன்னால் குலையுங்காண் - கூட்டிற்
சுரதோடந் தொண்டைநோய் தோலால் பித்தம்
பரதேசம் போயே பறந்து " . - அகத்தியர் குணவாகடம்.

15. கஸ்தூரி மஞ்சள் :

Botanical Name : Curcuma aromatica

Family : Zingiberaceae

Part used : Rhizome

சுவை : கைப்பு

வீரியம் : வெப்பம்

பிரிவு : கார்ப்பு

Therapeutic actions : Carminative, Stimulant

Chemical constituents : Curcumol, tetramethylpyrazine, neocurdione

பொதுகுணம் :

புண்ணுங் கரப்பானும் போகாக் கிருமிகளும்
நண்ணுமந் தாக்கினியு நாசமாய் - வண்ணமலர்த்
தொத்தே றுளகமின்னே சுக்கிலமும் புதியுமாங்
கஸ்தூரி மஞ்சளுக்குக் காண்.

- அகத்தியர் குணவாகடம்.

16. நல்லெண்ணெய் :

எள்

- எள்ளில் இருந்து நல்லெண்ணெய் தயாரிக்கப்படுகிறது.

Botanical Name : Sesamum indicium

Family : Pedaliaceae

Part used : Seed

சுவை : இனிப்பு

தன்மை : வெப்பம்

பிரிவு : இனிப்பு

Therapeutic actions : Demulcent, Nutritive, Laxative

Chemical constituents : 1-o-beta-D-glucopyranosyl, 3,4 dihydroxy-8-octadane

பொதுகுணம் :

” கண்ணுக்கு ஒளியையும் உடலுக்கு வன்மையும் தரும்

குருதிப் பெருக்கை உண்டாகும் ” .

- அகத்தியர் குணவாகடம்.

17. வெள்ளாட்டுப்பால் :

“சீதமதி சார்ட் சிலேஷ்மமறும் புண்ணாறும்

வாத சிலேஷமமுப்போ மாய்ந்து.

வெள்ளாட்டுப் பாலினால் வாத பித்த தொந்தம் , சுவாசகாசம், சீதாதிசாரம், கபதோஷம், விரணம், வாதத்திலுண்டாகிய வீக்கம் முதலியன தீரும்.

ANNEXURES -I

TRIAL DRUGS:

INTERNAL DRUG: VATHATHIRKU LEGHIYAM (Internal) **Ref**:(Athmaratchamirtham Pg 308)

PANCHARKA THYLAM (External)

Ref:(Agathiar mani ennum vathiya sithamani venba 4000 Pg 99)

Ingredients

VATHATHIRKU LEGHIYAM (internal)

Sl. No	DRUGS	BOTANCAL NAME	PART USED	AMOUNT
1	Poondu	Allium sativum	Bulb	1 Padi (1440 ml)
2	Chathipaththiri	Myristica fragrans	Aril	5 varagan (21 grm)
3	Sathikkai	Myristica fragrans	Seed	5 varagan (21 grm)
4	Seeragam	Cuminum cyminum	Fruit	5 varagan (21 grm)
5	Kirambu	Syzygium aromaticum	Flower bud	5 varagan (21 grm
6	Elam	Elettaria carda momum	Seed	5 varagan (21 grm)
7	Akkarakaram	Anacyclus Pyrethrum	Rhizome	5 varagan (21 grm)
8	Thipilimoolam	Piper longum	Root	5 varagan (21 grm)
9	Chukku	Zingiber officinale	Rhizome	5 varagan (21 grm)
10	Milagu	Piper nigrum	Seed	5 varagan (21 grm)
11	Thippili	Piper longum	Fruit	5 varagan (21 grm)
12	Omam	Carum copiticum	Seed	5 varagan (21 grm)
13	Parangipattai	Smilax China	Root	5 varagan (21 grm)
14	Nilapanaikizhangu	Curculigo orchioides	Rhizome	5 varagan (21 grm
15	Cow Milk			1Padi (1440 ml)
16	Nei (Ghee)			1Padi (1440 ml)
17	Then (Honey)			1 Padi (1440 ml)

Dose: Kottaipakalavu (6.022 gm)

Adjuvant: Milk

Duration: 40 days

Source of raw drugs:

The required raw drugs are purchased from authorized centers and standardized before preparing medicines .The raw drugs will be authenticated and then they are purified and the medicines are prepared in Gunapadam laboratory of Government Siddha Medical College, Palayamkottai.

PREPARATION:

Boil the Grartic in Cow's Milk and stir well add the above raw drugs to the above boiled milk finally add the Honey & stir well till reaches is consistency

DRUG STORAGE:

The trial drug **VATHATHIRKU LEGHIYAM** is stored in a clean and dry air tight container and it is dispensed to the patients in packets.

EXTERNAL DRUG:

PANCHARKA THYLAM (External)

Ref:(Agathiar mani ennum vathiya sithamani venba 4000 Pg 99)

Ingredients

Sl. No	**DRUGS**	**BOTANCAL NAME**	**PART USED**	**AMOUNT**
I	Erukkam Samoola Sarru	Calotropis gigantea	Whole Plant	1Nazhi – 1.34 litre
II	Amukkura	Withania somnifera	Rhizome	5 Palam (175 gm)
	Murungai	Moringa oleifera	Bark	5 Palam (175 gm)
	Veliparuthi	Pergularia daemia	Leaf	5 Palam (175 gm)
	Charanai	Trianthema Portulacastrum	Root	5 Palam (175 gm)
	Athandai	Capparis zeylanica	Root	5 Palam (175 gm)
	Notchi	Vitex negundo	Leaf	5 Palam (175 gm)
	Mukkirattai	Boerhaavia disffusa	Leaf	5 Palam (175 gm)
	Thanner (water)			1 Nazhi (1.34 litre)
III	Induppu	Sodium Chloride impura		1 Palam (35 gm)
	Thagarai Vithai	Cassia tora	Seed	1 Palam (35 gm)
	Kirambu	Syzygium aromaticum	Fruit	1 Palam (35 gm)
	Chukku	Zingiber offcinale	Rhizome	1 Palam (35 gm)
	Elakkai	Elettaria Caradamomum	Fruit	1 Palam (35 gm)
	Kottam	Costus specious	Root	1 Palam (35 gm)
	Kathuri Manjal	Curcuma aromatic	Rhizome	1 Palam (35 gm)
	Gingely oil	Sesamum indicum		5.36 liter
	Goat's milks			5.36 liter

METHOD OF PREPARATION :

Add water to no : II ingredients and make kudineer

Grind no : III ingredients and make into Karkam mix colotropis juice to the kudineer and add karkam also. Add gingely oil and white goats's milk, mix well and boil the oil finally filter the oil and keep if for use.

DRUG STORAGE:

The trial drug is stored in a clean dry air tight container and it is given to the patients in disposable pet bottles.

INDICATIONS:

It is indicated externally for Vatha diseases of Joint Pain

DISPENSING :

The Leghiyam are dispensed in airtight packets – Each packet contains 84gms

The oil is dispensed in a dry air tight bottles-for their required amount

For Outpatient one packet is given for seven days onces. (to be taken thrice daily)

For Inpatient every day the medicine packets will be dispensed in person.

ANNEXURES -II

QUALITATIVE AND QUANTITATIVE ANALYSIS

BIO-CHEMICAL ANALYSIS OF VATHATHIRKU LEGHIYAM

(IN POWDER FORM)

Preparation of the extract:

5gms of the drug was weighed accurately and placed in a 250ml clean beaker. Then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made to 100ml with distilled water. This fluid is taken for analysis.

QUALITATIVE ANALYSIS

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1.	**TEST FOR CALCIUM** 2ml of the above prepared extract is taken in a clean test tube to this add 2ml of 4% ammonium oxalate solution	No white precipitate is formed	Abesence of calcium
2.	**TEST FOR SULPHATE** 2ml of the extract is added to 5% barrium chloride solution.	A white precipitate is formed	**Indicates the presence of sulphate**
3.	**TEST FOR CHLORIDE** The extract is treated with silver nitrate solution	A white precipitate is formed	**Indicates the presence of chloride**
4.	**TEST FOR CARBONATE** The substance is treated with concentrated HCL.	No brisk effervescence is formed	Absence of carbonate
5.	**TEST FOR STARCH** The extract is added with weak iodine solution	No Blue colour is formed	Absence of starch
6.	**TEST FOR FERRIC IRON** The extract is acidified with glacial acetic acid and potassium ferro cyanide.	No blue colour is formed	Absence of ferric iron

7.	**TEST OF FERROUS IRON** The extract is treated with concentrated nitric acid and ammonium thiocyanide solution	Blood red colour is formed	**Indicates the presence of ferrous iron**
8.	**TEST FOR PHOSPHATE** The extract is treated with ammonium molybdate and concentrated nitric acid	No yellow precipitate is formed	Absence of phosphate
9.	**TEST FOR ALBUMIN** The extract is treated with esbach's reagent	No Yellow precipitate is formed	Absence of Albumin
10.	**TEST FOR TANNIC ACID** The extract is treated with ferric chloride.	No blue black precipitate is formed	Absence of tannic acid
11.	**TEST FOR UNSATURATION** Potassium permanganate solution is added to the extract	It gets decolourised.	**Indicates the presence of unsaturated compound**
12.	**TEST FOR THE REDUCING SUGAR** 5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8 to10 drops of the extract and again boil it for 2 minutes.	Colour change occurs.	**Indicates the presence of Reducing sugar**
13.	**TEST FOR AMINO ACID** One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% ninnhydrin is sprayed over the same and dried it well.	Violet colour is formed	**Indicates the presence of Amino acid**
14.	**TEST FOR ZINC** The extract is treated with Potassium ferrocyanide.	No white precipitate is formed	Absence of Zinc.

Inference: The given sample of "Vathathirku leghiyam" contains sulphate, chloride,ferrous iron, unsaturated compound, reducing sugar, amino acid.

PHARMACOLOGICAL ANALYSIS

EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON ACETIC ACID INDUCED WRITHING IN MICE[1]

1. Kaneria MS, Naik SR, Kohli RK. Anti-inflammatory,antiarthritic and analgesic activity of a herbal formulation. Indian J.Experimental Biol. 2007; 45: 279.

Acetic acid induced writhing method was adopted for evaluation of analgesic activity. Writhing is defined as a stretch, tension to one side, extension of hind legs, contraction of the abdomen so that the abdomen of mice touches the floor, turning of trunk (twist). Any writhing is considered as a positive response.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

DRUGS:

Acetic acid (Sigma Chemical Co. Bangalore, India) and Indomethacin were purchased from (Ranbaxy, India). All drugs were dissolved in saline. The different doses of **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**.The control group received vehicle as control. All drugs were prepared just before use.

PREPARATION OF ACETIC ACID:

A solution of acetic acid (1% v/v) in distilled water was prepared.

DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 30 gm of mice

6000 mg x 2(a) x 0.018 (b) = 108 (c) /30 gm of mice

108/1000x30 = 3.24 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	0.5 ml
2	Therapeutic Dose	3.24 mg /kg	0.5 ml
3	Middle Dose	16.2mg/kg	0.5 ml
4	High Dose	81mg/kg	0.5 ml

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL (IP injection of 0.1 ml 1% acetic acid)

GROUP 2 -- IP injection of 0.1 ml 1% acetic acid + Indomethacin (5mg/kg, i.p)

GROUP 3 -- 0.1 ml 1% acetic acid (ip) + VATHATHIRKU LEGHIYAM WITH HONEY/GHEE **3.24MG /KG(PO)**

GROUP 4 -- 0.1 ml 1% acetic acid (ip) + VATHATHIRKU LEGHIYAM WITH HONEY/GHEE **16.2mg/Kg(Po)**

GROUP 5 -- 0.1 ml 1% acetic acid (ip) + VATHATHIRKU LEGHIYAM WITH HONEY/GHEE **81mg/kg(po)**

PROCEDURE:

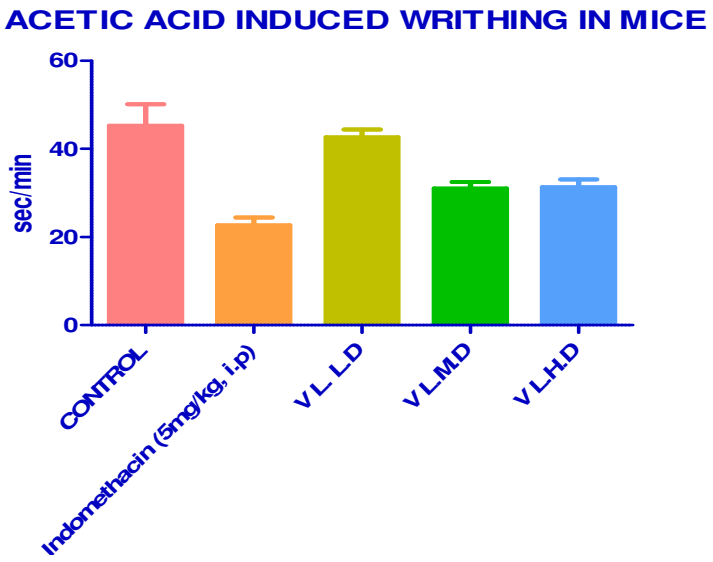
Wister albino mice of either sex were divided into five different groups each containing Six animals, the animals were marked individually. Food was withdrawn 12 hours prior to drug administration till completion of experiment. The animals were weighed and numbered appropriately. The test and standard drugs were given orally. After 60 minutes writhing was induced by intra-peritoneal injection of 1% acetic acid in volume of 0.1 ml/10g body weight. The writhing episodes were recorded for 30 minutes; stretching movements consisting of arching of the back, elongation of body and extension of hind limbs were counted. Anti-nociceptive activity was expressed as the percentage inhibition of abdominal constrictions using the ratio:

(Control mean – Treated mean) × 100/Control mean

EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON ACETIC ACID INDUCED WRITHING IN MICE[1]

GROUP	No of Writhing (30min)	Inhibition (%)
CONTROL	45.33±4.807	----
Indomethacin (5mg/kg, i.p)	22.67±1.764	49.98 %
VATHATHIRKULEGHIYAM 0.028mg/kg(po)	42.67±1.764	5.86 %
VATHATHIRKULEGHIYAM 0.014mg/kg(po)	31±1.528	31.61 %
VATHATHIRKULEGHIYAM 0.28mg/kg(po)	31.33±1.764	30.88 %

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON HOT PLATE METHOD IN MICE[1]

1. Turner RA. Screening methods in pharmacology. In: Turner, R., Hebborn, P. (eds.). Academic press, New York. 1965; 100.

The paws of mice and rats are very sensitive to heat at temperatures which are not damaging the skin. The responses are jumping, withdrawal of the paws and licking of the paws.

MATERIAL AND METHODS

ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore

(685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

The hot plate, which is commercially available, consists of a electrically heated surface. The temperature is controlled for 55° to 56 °C. This can be a copper plate or a heated glass surface. The animals are placed on the hot plate and the time until either licking or jumping occurs is recorded by a stop-watch.

EXPERIMENTAL PROCEUDRE:

GROUP 1 – CONTROL

GROUP 2 – Pentazocine (10mg/kg, I.P)

GROUP 3 -- VATHATHIRKU LEGHIYAM WITH HONEY/GHEE
3.24 mg /kg(po)

GROUP 4 – VATHATHIRKU LEGHIYAM WITH HONEY/GHEE
16.2mg/kg(po)

GROUP 5 -- VATHATHIRKU LEGHIYAM WITH HONEY/GHEE
81mg/kg(po)

PROCEUDRE:

Mice were screened by placing them on a hot plate maintained at 55±1ºC and recording the reaction time in seconds for forepaw licking or jumping. Only mice which reacted within 15sec and which did not show large variation when tested on four separate occasions, each 15min apart, were taken for the test. The time for forepaw licking or jumping on the heated plate of the analgesiometer maintains at 55ºC was taken as the reaction time.

Prior to treatment, the reaction time of each mouse (licking of the forepaws or jumping response) was done at 0- and 10-min interval. The average of the two readings was obtained as the initial reaction time (*Tb*). The reaction time (*Ta*) following the administration of the ----------, Pentazocine and distilled water was measured at 0.5, 1, 2, and 3h after latency period of 30min.

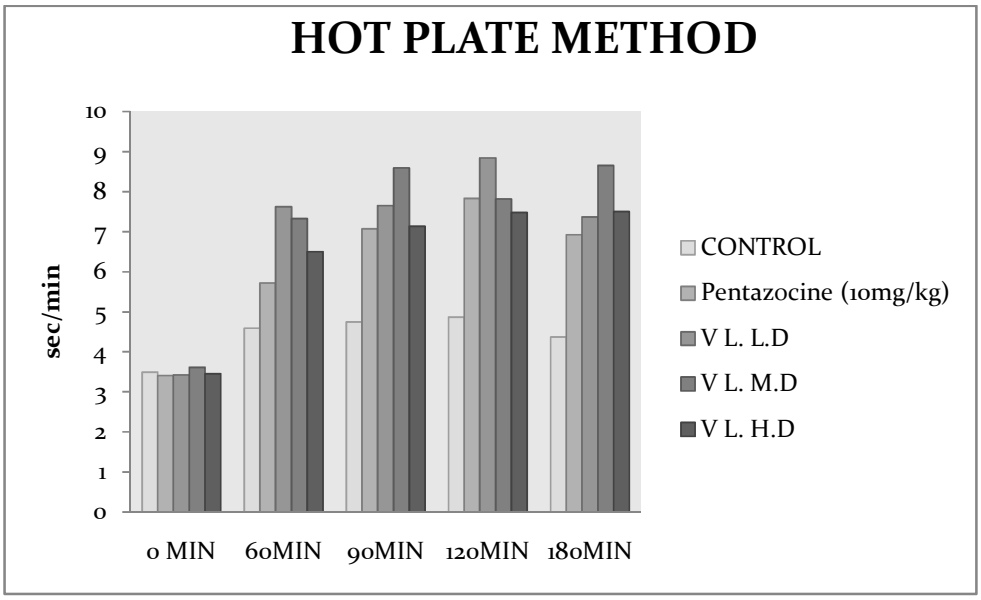
The following calculation was:

Percentage analgesic activity = $Ta\text{-}Tb/Tb \times 100$

EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON HOT PLATE METHOD IN MICE:-

GROUP	Reaction time in seconds at time (minutes) (mean ± sem) (mean ± sem)				
	O mints	60 mints	90 mints	120 mints	180 mints
CONTROL	3.497±0.1114	4.59±0.165	4.75±0.083	4.87±0.049	4.37±0.098
STANDARD	3.413±0.1598	5.77±0.039**	7.077±0.13***	7.83±0.061***	6.92±0.22***
V L + LOW DOSE	3.42±0.1804	7.627±0.15***	7.65±0.17***	8.87±0.043***	7.37±0.11***
V L + MIDDLE DOSE	3.613±0.06888	7.37±0.23***	8.59±0.168***	7.82±0.118***	8.66±0.14***
V L+ HIGH DOSE	3.453±0.1642	6.5±0.115***	7.13±0.072***	7.48±0.18***	7.50±0.27***

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's $^{***}P< 0.001$, $^{**}P < 0.01$, $^{*}P < 0.05$ calculated by comparing treated group with CONTROL group.



EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON CARRAGEENAN-INDUCED LOCALISED INFLAMMATORY PAIN IN RATS

SUMMARY

The study plan was developed based on the guidelines of Vogel[1] and also it has reference to Chao Ma and Jun-Ming Zhang[2] and Walker et al. [3,] Winter CA, Risley EA, Nuss GW. Carrageenin induced edema in hind paw of the rat as an assay for anti-inflammatory drugs. Proc Soc Exp Biol Med. 1962;111:544–7.

Objective

To study the anti-inflammatory effect of **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE** in the rat model of Carrageenan-induced localized inflammation.

Methods:

Test System

Species	:	Rat
Strain	:	Albino Wister
Age	:	6-8 weeks at the time of dosing

Total no. of Rats : 24

Sex : Male

Weight : 150 gm

The animals were housed in polypropylene cages with stainless steel top grills having facilities for holding pellet food and drinking water in bottle with stainless steel sipper tube. Each cage contained 6 rats. All rats had free access to potable water and standard pelleted laboratory animal diet *ad libitum*. Paddy husk was used as bedding material. The animals were divided into 5 groups (6 rats/group). Localized inflammatory pain was induced in all groups of animals by intraplantar injection of carrageenan (50 µl of 3% suspension).

One day before the experiment, three basal readings of hind paw in each rat were recorded. Group 1 received vehicle orally, Group 2 received a standard drug Diclofenac sodium (10 mg/kg i.p), whereas groups 3,4and 5 received **VATHATHIRKU LEGHIYAM**. The doses of **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**, whereas Diclofenac sodium was dissolved in normal saline. After 30 min, the rats were challenged with subcutaneous injection of 0.1 ml of 1% w/v solution of carrageenan into the sub plantar region of left paw. The paw was marked with ink at the level of lateral malleolus and immersed in mercury up to the mark. The paw volume was measured at 0, 1, 2, 3, 4, 5 and 6^{th} hr after carrageenin injection using Digital Plethysmometer. The difference between initial and subsequent reading gave the actual edema volume.

DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

6000 mg x 2(a) x 0.018 (b) = 108 (c) /150 gm of Rat

108/1000x150 = 16.2 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	16.2 mg /kg	1 ml
3	Middle Dose	81mg/kg	1 ml
4	High Dose	405mg/kg	1 ml

EXPERIMENTAL DESIGN:

Group-I: Served as a negative control (0.1ml of 1% carrageenin)

Group-II: Served as standard received Diclofenac sodium (10mg/kg, i.p) +

(0.1ml of 1% carrageenin)

Group-III: Received **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**

(16.2 mg /kg) + (0.1ml of 1% carrageenin)

Group IV: Received **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**

(81 mg/kg) + (0.1ml of 1% carrageenin)

Group V: Received **VATHATHIRKU LEGHIYAM** were prepared **WITH HONEY/GHEE**

(405 mg/kg) + (0.1ml of 1% carrageenin)

TABLE: EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON Carrageenin - INDUCED PAW EDEMA IN RATS (BODY WEIGHT in gms)

Group	Only Carrageenin	Carrageenin + STD	Carrageenin + L.D	Carrageenin + M.D	Carrageenin + H.D
INITIAL BODY WEIGHT	156.7±1.333	142.3±28.48	161±4.973	166.3±2.813	151.5±3.191

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group.

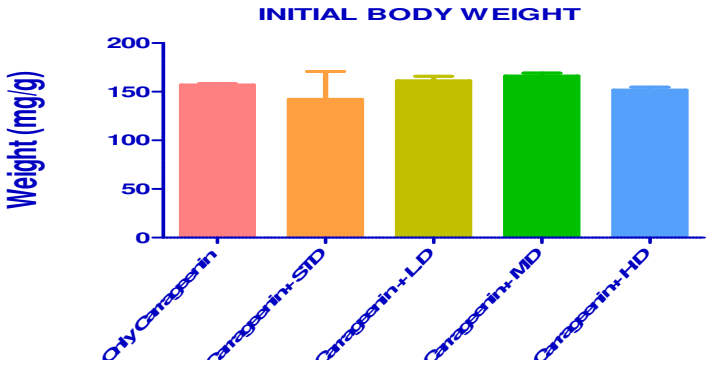


TABLE: EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON Carrageenin - INDUCED PAW EDEMA IN RATS

Group	Mean paw volume before Carrageenin injection	Paw Volume after induction with Carrageenin Increase in paw volume (ml) after Carrageenin injection (mean ± SEM)/Percent inhibition of edema						
	0 min	30 min	1h	2h	3h	4h	5h	6h
Control	4.105± 0.1627	7.425± 0.1594	7.483± 0.1429	8.348± 0.2079	8.39± 0.1014	7.86± 0.0801	8.283± 0.2986	7.913± 0.2277
Standard	4.085± 0.1617	7.033± 0.1053	7.813± 0.1993	7.79± 0.249	7.958± 0.2091	7.788± 0.1251	6.033± 0.1574	5.663± 0.2765
LD	3.698± 0.258	6.973± 0.1963	7.648± 0.1579	8.153± 0.2022	8.105± 0.1269	7.448± 0.2509	6.638± 0.3813	6.1± 0.2967
MD	4.283± 0.09437	7.068± 0.1006	7.488± 0.2231	7.8± 0.1545	8.16± 0.1066	7.75± 0.03764	6.235± 0.1546	5.49± 0.1828
HD	4.028± 0.2623	7.108± 0.3236	7.66± 0.3129	6.893± 0.3936**	7.335± 0.2522**	6.94± 0.1685	6.17± 0.1339	5.003± 0.2594

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group.

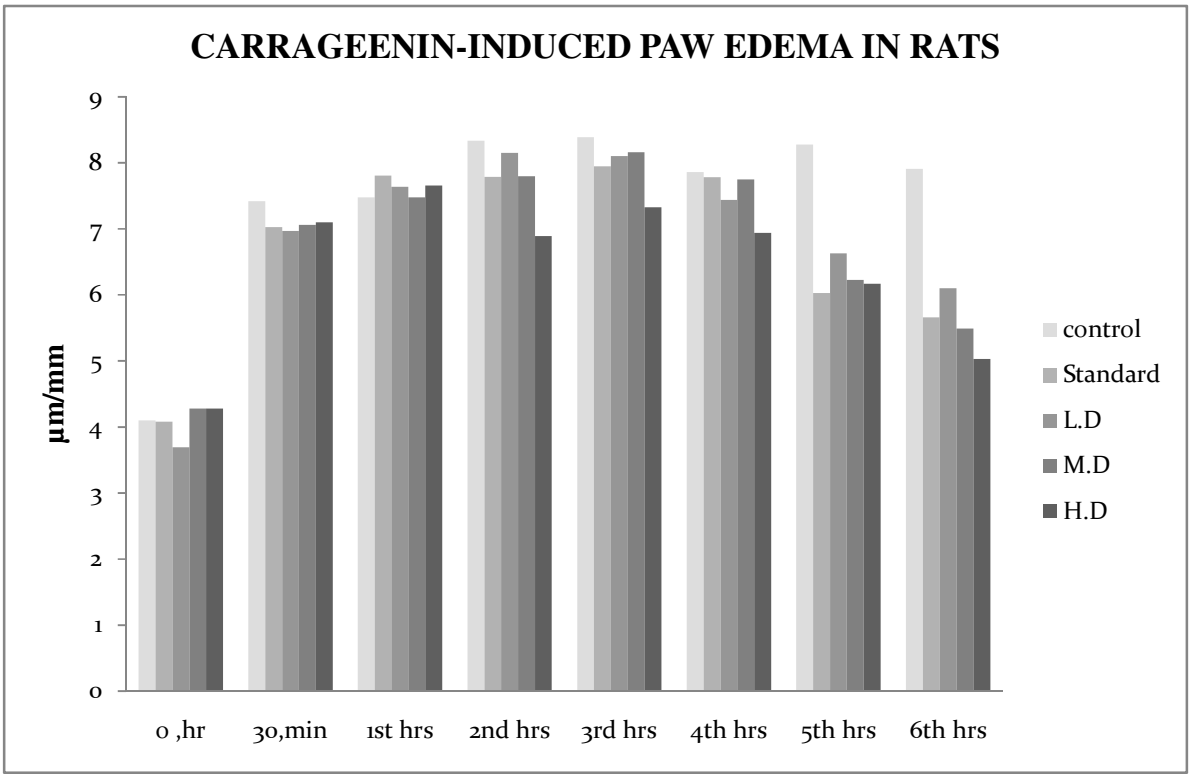
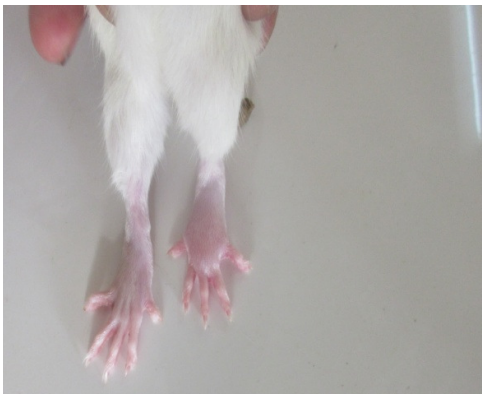

CARRAGEENIN-INDUCED PAW EDEMA IN RATS
µm/mm
9
8
7
6
5
4
3
2
1
0
0 ,hr
30,min
1st hrs
2nd hrs
3rd hrs
4th hrs
5th hrs
6th hrs
control
Standard
L.D
M.D
H.D

FIG: EFFECT OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON CARRAGEENIN-INDUCED PAW EDEMA IN RATS



GROUP – I ONLY CARRAGEENIN

GROUP –II CARRAGEENIN + STD

GROUP –III CARRAGEENIN + L.D

GROUP –IV CARRAGEENIN +MD

GROUP –V CARRAGEENIN + H D

ACUTE TOXICITY STUDY IN FEMALE WISTER RATS TO EVALUATE TOXICITY PROFILE OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE

Table 1. Test substance details

Name of the test substance	**VATHATHIRKU LEGHIYAM With Honey/Ghee**
Colour of the test substance	-Light brown
Nature of the test substance	Powder

Table 2. Experimental protocol

Name of the study	Acute toxicity
Guideline followed	OECD 423 method-acute toxic class method
Animals	Healthy young adult female wister rats, nulliparous, non-pregnant
Body weight	150-200 g
Sex	female
Administration of dose and volume	6000 mg/kg in 200g body weight, single dose in 1 ml
Number of groups and animals	5 groups and 3 animals in each group 1000,2000,3000,5000and 6000mg/kg
Route of administration	Oral Cavage (po)
Vechicle	Honey/Ghee

Table3. Housing and feeding conditions

Room temperature	22°C ± 3°C
Humidity	40-60%
Light	12 h : 12h (light : dark cycle)
Feed	Standard laboratory animal food pellets with water *ad libitum*

Table 4. Study period and observation parameters

Initial once observation	First 30 minutes and periodically 24 h
Special attention	First 1-4 h after drug administration
Long term observation	Upto 14 days
Direct observation parameters	Tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma.
Additional observation parameters	Skin and fur, eyes and mucous membrane, respiratory, circulatory, autonomic and central nervous systems, somato motor activity and behavior pattern etc.

The time of death, if any, is recorded. (Complete observations: annexure I). After administration of the drug, food is withheld for a further 1-2 hours.

Study procedure

Acute oral toxicity was performed as per organization for economic co-operation for development (OECD) guideline 423 method. The **VATHATHIRKU LEGHIYAM With Honey/Ghee** was administered in a single dose by tuberculin syringe. Animals are fasted 3 h prior to dosing (food was withheld for 3 h but not water). Following the period of fasting animals was weighed and test substance was administered orally at a dose of 1000,2000,3000,5000 and 6000mg/kg. After the **VATHATHIRKU LEGHIYAM With Honey/Ghee** administration, food was withheld 2 h in mice. Animals are observed individually after at least once during the first 30 minutes, periodically during the first 24 hrs, with special attention given during the first 4 hrs, and daily thereafter, for a total of 14 days.

REPORT

Toxicological evaluation of VATHATHIRKU LEGHIYAM with Honey/Ghee

Table:5 Effect of **VATHATHIRKU LEGHIYAM With Honey/Ghee** on acute toxicity test in female rats.

S.N	Response	Head		Body		Tail	
		Before	After	Before	After	Before	After
1	Alertness	Normal	Normal	Normal	Normal	Normal	Normal
2	Grooming	Absent	Absent	Absent	Absent	Absent	Absent
3	Touch response	Absent	Absent	Absent	Absent	Absent	Absent
4	Torch response	Normal	Normal	Normal	Normal	Normal	Normal
5	Pain response	Normal	Normal	Normal	Normal	Normal	Normal
6	Tremors	Absent	Absent	Absent	Absent	Absent	Absent
7	Convulsion	Absent	Absent	Absent	Absent	Absent	Absent
8	Righting reflux	Normal	Normal	Normal	Normal	Normal	Normal
9	Gripping strength	Normal	Normal	Normal	Normal	Normal	Normal
10	Pinna reflux	Present	Present	Present	Present	Present	Present
11	Corneal reflux	Present	Present	Present	Present	Present	Present
12	Writhing	Absent	Absent	Absent	Absent	Absent	Absent
13	Pupils	Normal	Normal	Normal	Normal	Normal	Normal
14	Urination	Normal	Normal	Normal	Normal	Normal	Normal
15	Salivation	Normal	Normal	Normal	Normal	Normal	Normal
16	Skin colour	Normal	Normal	Normal	Normal	Normal	Normal
17	Lacrimation	Normal	Normal	Normal	Normal	Normal	Normal

RESULT:

From acute toxicity study it was observed that the administration of **VATHATHIRKU LEGHIYAM with Honey/Ghee** to Female Wister rats did not induce drug-related toxicity and mortality in the animals up to 6000mg/kg in 200g female Wister rats. So No-Observed-Adverse-Effect- Level (NOAEL) of

VATHATHIRKU LEGHIYAM with Honey/Ghee is 6000 mg/kg equal to human dose

DISCUSSION

VATHATHIRKU LEGHIYAM with Honey/Ghee was administered single time at the doses of 1000,2000,3000,5000 and 6000mg/kg to female Wister rats and observed for consecutive 14 days after administration. Doses were selected based on the pilot study and literature review. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded. No mortality was observed during the entire period of the study. Data obtained in this study indicated no significance physical and behavioral signs of any toxicity due to administration of **VATHATHIRKU LEGHIYAM with Honey/Ghee** at the doses of 1000,2000,3000,5000 and 6000mg/kg to female Wister rats

At the 14th day, all animals were observed for functional and behavioral examination. In functional and behavioral examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, Clonic involuntary movement, Tonic involuntary movement, Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities like Reactivity, Handling, Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioral examination was normal in all treated groups. Food consumption of all treated animals was found normal as compared to normal group.

SUMMARY & CONCLUSION:

Summary:

The present study was conducted to know single dose toxicity of **VATHATHIRKU LEGHIYAM with Honey/Ghee** on female Wister rats. The study was conducted using 15 female Wister rats. The female animals were selected for study of 8- 12 weeks old with weight range of within ± 20 % of mean body weight at the time of randomization. The groups were numbered as group I, II, III, IV and V and dose with **1000,2000,3000,5000 and 6000mg/kg** of **VATHATHIRKU LEGHIYAM with Honey/Ghee**. The drug was administered by oral route single time and observed for 14 days. Daily the animals were observed for clinical signs and mortality.

There were no physical and behavioral changes observed in Female Wister rats during 14 days. Mortality was not observed in any treatment groups.

Conclusion:

The study shows that **VATHATHIRKU LEGHIYAM with Honey/Ghee** did not produce any toxic effect at dose of **1000,2000,3000,5000 and 6000mg/kg** to rats. So No-Observed-Adverse-Effect-Level (NOAEL) of **VATHATHIRKU LEGHIYAM with Honey/Ghee** is 6000 mg/kg.

7.0 ABBREVIATIONS

No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o	peros
ML	Milliliter
%	percentage
R&D	Research and Development
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level

MLD Minimum Lethal Dose
MTD Maximum Tolerated Dose
OECD Organisation of Economic Co-operation and Development
CPCSEA Committee for the Purpose of Control and Supervision of Experiments on Animals

8.0 REFERENCES:

1. OECD. Guideline for Testing of Chemicals 423, Acute oral toxicity (acute toxic class method). December 2001.

SUB-ACUTE TOXICITY STUDY IN WISTER RATS TO EVALUATE TOXICITY PROFILE OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE

Objective

The objective of this study is to evaluate the toxic effects, if any, as a result of the repeated once daily oral administration of **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE** to Wister Albino rats for a minimum period of 28 consecutive days. This study will provide information on any major toxic effects, target organs and a rationale for concluding the No-Observed-Adverse-Effect-Level (NOAEL) and/or No Observed Effect Level (NOEL) / LOEL (Low Observed Effect Level) and risk assessment in humans.

1. Test Guidelines

This study plan is prepared as per the following guidelines:

Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

OECD – 407 – Repeated dose 28-day Oral Toxicity Study in Rodents, Adopted 3 October, 2008.

1.1. Test System Details

Species	:	Rat
Strain	:	Wister Albino
Source	:	Sree Venkateshwara Enterprises Pvt Ltd, Bangalore
Age	:	6-8 weeks
Sex	:	Male / Female (nulliparous and non-pregnant)
Body weight	:	160.0to 180.0 g

1.2. Acclimatization

Animals will be allowed to acclimatize to the experimental room conditions for five days prior to the commencement of dosing. During the acclimatization period, the animals will be observed daily for any apparent adverse clinical signs. Prior to assignment to the study and commencement of treatment, a detailed physical health examination will be performed on all animals by a veterinarian and animals with any evidence of ill health or poor physical condition will not selected for the study.

1.3. Randomization and Grouping

On the starting day of dosing, the animals will be weighed and health examination will be performed by veterinarian. Animals will be randomly allocated to different groups according to their body weight by using MS-Excel sheet as described in the randomization SOP. Animals will be divided into four groups (vehicle control, low, intermediate, and high dose). At the initiation of the treatment, the body weight variation between the groups did not exceed ±20% of the mean weight of each sex.

1.4. Animal Identification

In each cage, animals will be identified with numbers by marking at the base of the ear. The cages will be identified with an attached colored cage label showing study number, study code, group number, sex, dose, strain, species, cage number, route of administration and animal number.

2. Animal Husbandry

2.1. Animal Welfare and approval

The study was approved by the IAEC (SLS) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA registration number: Abc14).Their recommendations regarding animal care and handling will be followed.

2.2. Environmental Conditions

The temperature of the experimental room will be maintained at 22±3^{0}C and the relative humidity between 30-70 %. The photoperiod will be 12 hours light and 12 hours dark cycles

2.3. Housing Conditions

Two animals will be housed in autoclaved polypropylene rat cages (Size in mm=L x W x H: 430 x 290 x 160) using paddy husk as the bedding material. Each cage will be fitted with a top grill having provision for keeping rodent pellet feed and an autoclaved polypropylene water bottle with stainless steel drinking nozzle. Cages will be placed on 3-tier racks and cage rotation will be performed every week. Cages will be changed at least twice a week. The cages and water bottles will be cleaned and autoclave sterilized.

2.4. Sanitation

Each day, the floor of the animal room will be swept and mopped. Cages and bedding material will be changed once in three days and water bottles will be changed daily. All the experimental procedures will be done in a clean environment.

2.5. Feed

The experimental animals will be provided with irradiated rodent pellet feed *ad libitum* supplied from Sai feeds Pvt ltd, Chennai . Feed will be withheld for four hours prior to blood collection and necropsy.

2.6. Drinking Water

Animals will be provided with filtered drinking water *ad libitum* passed through water filter system (Aquaguard™) in autoclaved polypropylene bottles. Water bottles will be changed daily. Microbial analysis of water will be carried out once monthly and the report is maintained in the study file.

3. Personnel Safety

All personnel handling animals undergo regular medical examination. Protective clothing like apron, face mask, head cap, and gloves will be used to maintain hygienic conditions.

4. Materials and Methods

4.1. Preparation of Dose formulation

The dose formulation will be prepared under aseptic conditions as per SLS, SOP.

4.2. Route of Administration and Justification

Administration will be by oral gavage, as it is one of the possible routes of exposure.

4.3. Frequency and Duration of Administration

Once daily for 28 consecutive days

4.4. Dosing Procedure

The test item will be administered in once daily by oral gavage using a suitable intubation cannula fitted with a graduated syringe. The scheme of dosing and sacrifice time points are presented in the below below Table.

4.5. Experimental Procedures

All experimental procedures will be performed in accordance with the Study plan and Standard Operating Procedures (SOPs) of SLS.

4.6 DOSAGE SCHEDULE:

The required dose for mice/rat will be calculated by using the standard dose calculation procedure from recommended clinical dose.

CONVERSION FORMULA:

Human dose is 6000 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

6000 mg x 2(a) x 0.018 (b) = 108 (c) /150 gm of Rat

108/1000x150 = 16.2 mg

Experimental Doses Calculated as per the standard procedures are

S.No	Groups	Dose /kg, weight	Volume of administration
1	Vehicle Control	--	1 ml
2	Therapeutic Dose	16.2 mg /kg	1 ml
3	Middle Dose	81mg/kg	1 ml
4	High Dose	405mg/kg	1 ml

Experimental Design

Group No.	Group	Dose (mg/kg b.wt /day)	No. of Animals	
			Male	Female
G1	Vehicle control	**HONEY/GHEE**	5	5
G2	Low dose of **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE**	16.2m g /kg	5	5
G3	Intermediate dose **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE**	81mg/kg	5	5
G4	High dose **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE**	405mg/kg	5	5

5. Observations

Animals will be observed daily throughout the treatment period at regular intervals. During the treatment period, animals will be observed twice daily for any clinical signs of toxicity, morbidity and mortality. All the surviving animals will be sacrificed at the end of scheduled period and subjected to gross necropsy and histopathological evaluations.

5.1.Clinical Signs

All the animals will be subjected to cage-side (home-cage) observations twice a day for any clinical signs of toxicity, preferably at the same time each day and considering the peak period of anticipated effect. In addition to home cage observations, a detailed clinical examination will be performed once prior to dosing and weekly thereafter during treatment period.

5.2. Morbidity/ Mortality

All animals will be examined twice a day for mortality and signs of morbidity.

5.3. Body Weights

Body weights will be recorded at the beginning of acclimatization, before randomization, there after at weekly intervals and at the time of necropsy.

5.4. Feed Consumption

Feed consumption will be calculated on a weekly basis throughout the study period.

5.5. Hematology and Clinical Biochemistry

Hematology and clinical biochemistry tests will be performed with terminally collected blood samples on day-29 from all animals. Animals will be deprived of feed overnight and blood samples will be collected by tapping the ear for visibility of the vein site and inserted the needle into the marginal ear vein and collected the blood into micro centrifuge tube. Approximately 0.5 ml of blood will be collected in vials containing 1% EDTA (20µl) as an anticoagulant for hematological analysis.

Approximately 2 ml blood will be collected from each animal in micro centrifuge tubes containing 15µl of heparin (19 units) and the plasma will be separated by centrifugation at 4000 rpm for ten minutes at 4^{o}C. The plasma will be stored at -20 ^{o}C ± 2 and used for all clinical chemistry analysis.

5.6. Hematology

Erythrocyte count (RBC), Total Leucocyte count (WBC), Hemoglobin (Hb), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Platelet (PLTC).

5.7. Clinical Biochemistry

Glucose, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline phosphatase (ALP), Total protein, Albumin, Creatinine, Urea, Cholesterol, Triglycerides, Sodium, Potassium, Calcium, and Chloride.

5.8 Pathology

All animals will be euthanized by CO_2 asphyxiation and subjected to necropsy under the supervision of the veterinary pathologist. Different tissues/organs of thoracic, abdominal and cranial cavities will be examined for any gross pathological changes. Tissues from vehicle control and high dose groups will be subjected to detailed histopathological analysis (Ovaries/ testes, kidneys, liver, lungs). The organs will be fixed using Bouin's (reproductive organs) and 10% neutral buffered formalin (kidneys, liver, spleen, lungs).Processing of tissue will be done by spin tissue processer, embedding of the tissue by tissue embedder. The tissues will be initially trimmed to 10-20µ thickness and later 3-6µ to obtain thinner tissue sections by using rotary microtome. Haematoxylin and Eosin staining will be performed for all tissues.

5.8. Organ Weights

Absolute weights of adrenal glands, brain, ovaries/testes, epididymis/uterus, heart, kidneys, liver, spleen and lungs will be recorded for all the animals after trimming adherent tissue immediately after dissection from the animal. Paired organs will be weighed together. Relative weights of these organs against fasting animal body weights will be calculated and reported.

6. Data Compilation

Data will be summarised in a tabular form showing the number of animals, experimental design, dose groups, dose volume and concentrations, test item and vehicle control details. All findings like clinical signs, mortality and morbidity data, time of death, body weights, feed consumption, clinical signs, and necropsy and pathology observations will be recorded and given in the final report. One original copy of the final report is issued to the sponsor.

7. Statistical Analysis

All the parameters of treated groups of both sex, viz. body weight, feed consumption, organ weights (absolute and relative), biochemical parameters, and hematology parameters will be analyzed using SPSS software, version 16.0 by using one-way ANOVA test with multiple comparison (vehicle controls treated groups) in the study report, and p value < 0.05 is considered as statistically significant.

8. References

1. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for Laboratory Animal Facility, The Gazette of India, 1998.
2. Hayes AW, 2000. Principles and Methods of Toxicology, 4th ed., Taylor and Francis, London.
3. Karl-Heinz Diehl, R. H. (2001). A Good Practice Guide to the Administration of Substances and Removal of Blood, Including Routes and Volumes. journal of applied toxicology , 15-23.
4. OECD – 407 - Repeated dose 28-day oral Toxicity Study in Rodents, Adopted October 3, 2008.
5. Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

MATERIALS AND METHODS

ESTIMATION OF HEMATOLOGICAL PARAMETERS: [1]

Collection of blood for hematological studies

After the treatment period the animals were anaesthetized by ketamine hydrochloride and the blood was collected from Retro-orbital sinus by using capillary into a centrifugation tube which contains EDTA for haematological parameters The haematological parameters like RBC, WBC and Hb percentage, Differential cell count, MCV, MCHC, Hematocrit, MCH, platelet count were estimated by the following procedures.

1. ENUMERATION OF RED BLOOD CELLS: [1] Ramnic 2007)

Reagents : RBC diluting fluid

Procedure:

Using a red blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and RBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried. Using 45X or high power objective the RBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells $x10^{12}/l$

2. ENUMERATION OF WBC: [2] John 1972)

Reagents:

Turk's fluid: Turk's fluid was prepared by mixing 2ml of acetic acid with 100 ml of distilled water. To this 10 drop of aqueous methylene blue 3 % w/v) was added. This solution haemolysis the red cells due to acidity so that counting of white cells becomes easy.

Procedure:

Using a white blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and WBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried.

Using 10X or low power objective the WBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells/10mm.

3. DIFFERENTIAL LEUCOCYTE COUNT: [3] John 1972)

Reagent:

Leishmann's stain: 150mg of powdered leishmann's stain was dissolved in 133ml of acetone free methanol.

Procedure:

A blood film stained with leishmann's stain was examined under oil immersion and the different types of WBCs were identified. The percentage distribution of these cells was then determined. Smears were made from anticoagulant blood specimens and stained with leishmann's stain. The slides were preserved for counting the number of lymphocytes and neutrophils, per 100 cells were noted.

From the different Leukocyte count and WBC count, absolute lymphocyte and neutrophil count were calculated.

$$\text{Absolute neutrophil count} = \frac{\text{Number of neutrophils}}{100} \times \text{TWBC}$$

$$\text{Absolute lymphocyte count} = \frac{\text{Number of lymphocytes}}{100} \times \text{TWBC}$$

DETERMINATION OF BIOCHEMICAL PARAMETERS:

For assessment of biochemical parameters, blood samples were collected from the animals by puncturing the retro-orbital plexus and centrifuged. The serum collected after centrifugation was analyzed for various biochemical parameters like SGOT, SGPT, ALP,TC.TG,HDL All of the above biochemical parameters were estimated using semi autoanalyzer (Photometer 5010 $_{V5+}$, Germany) with enzymatic kits procured from Piramal Healthcare limited, Lab Diagnostic Division, Mumbai, India.

1. Total Cholesterol (TC)

Principle

Determination of cholesterol is done after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (trinder's reaction).

$$\text{Cholesterol ester} + H_2O \xrightarrow{CHE} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{CHO} \text{Cholesterol-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine} + \text{Phenol} \xrightarrow{POD} \text{Quinonelimine} + 4\ H_2O_2$$

Method

CHOD-PAP: Enzymatic photometric test

Table 6: Reagents

Goods buffer (pH 6.7)	50 mmol/ l
Phenol	5 mmol/l
4-aminoantipyrine	0.3 mmol/l
Cholesterol estrase	> 200 U/l
Cholesterol oxidase	> 100 U/l
Peroxidase	3 KU/l
Standard	(5.2 mmol/l)

Assay procedure

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 5 min.
d. Read the test sample.

NORMAL RANGE: < 200 mg/dl in serum.

1. Deeg R, Ziegenhorn J, Kinetic enzymatic method for automated determination of total cholesterol in serum, Clin. Chem., 1983, 29:1798-802.

2. Triglycerides

Principle

Determination of triglycerides (TG) alters enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine which is generated from 4-aminoantipyrine and 4- chlorophenol by hydrogen peroxidase under the catalytic action of peroxidase.

$$\text{Triglycerides} \xrightarrow{\text{LPL}} \text{Glycerol + fatty acid}$$

$$\text{Glycerol + ATP} \xrightarrow{\text{GK}} \text{Glycerol-3-phosphate+ ADP}$$

$$\text{Glycerol-3-phosphate} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyaceton phosphate} + H_2O_2$$

$$2H_2O_2 + \text{4- Amino antipyrine + 4- chlorophenol} \xrightarrow{\text{POD}} \text{Quinonelimine + HCL} + 4H_2O_2$$

Method

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO).

Reagents

Components and concentrations in the test Goods buffer pH 7.2, 50 mmol/ l

Table 7: Reagents

4-chloroPhenol	4 mmol/l
ATP	2 mmol/l
Mg^{2+}	15 mmol/l
Glycerokinase	> 0.4 Kμ/l
Peroxidase	> 2 Kμ/l
Lipoprotein lipase	> 4 Kμ/l
4-aminoantipyrine	0.5 mmol/l
Glcerol-3-phosphate- oxidase	> 1.5Kμ/l
Standard	(2.3 mmol/l)

Assay procedure

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: < 200 mg/dl in serum.

1. Cole T.G, Klotzsch S.G, Mcnarmara J, Measurement of triglyceride concentration, In Rifai N, Warnick G.R, Dominiczak M.H, Handbook of lipoprotein testing, Washington:AACC, Press, 1997, 115-26.

3. HDL Cholestrol

Principle

Chylomicrons, VLDL and LDL are precipitated by adding phosphotungstic acid and magnesium ions to the sample. Centrifugation leaves only the HDL in the supernatant. The cholesterol content in it is determined enzymatically.

Method

Phosphotungstic acid precipitation method.

Table 8: Reagents

Phosphotungstic acid	0.55 mmol/l
Magnesium chloride	25 mmol/l

Assay procedure

A. Preparation of supernatant for the HDL-CHL estimation

Added 200 µl of serum to the 500 µl of HDL-Cholesterol precipitating reagent (from HDL kit) in 1.5 ml centrifuge tube and mixed well. Centrifuged the above solution at 4000 rpm for 10 min.

B. Preparation of test sample for the estimation of HDL-Cholesterol

a. Taken 1000 µl of reagent-1 (from cholesterol kit) in a 5 ml test tube.
b. Added, 100 µl of supernatant from above centrifuged solution
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

Normal Range: > 60 mg/dl in serum.

1. Friedewald W.T, Levy R.T, Frederickson D.S, Estimation of VLDL and LDL cholesterol, Clin. Chem., 1972, 18:499-502.

4. ESTIMATION OF SERUM GLUTAMATE PYRUVATE TRANSAMINASES (SGPT/ ALT)

1. Determination of aspartate aminotransferase (AST)

Aspartate aminotransferase, also known as Glutamate Oxaloacetate Transaminase (GOT) catalyses the transamination of L-aspartate and α keto glutarate to form oxaloacetate and L- glutamate. Oxaloacetate formed is coupled with 2,4- Dinitrophenyl hydrazine to form hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered aspartate (pH 7.4); 2,4- DNPH reagent; 4N sodium hydroxide; working pyruvate standard; solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was adopted for the estimation of SGOT. (Reitmann S, Frankel S, 1957. A colorimetric method for the determination of serum oxaloacetic and glutamic pyruvate transminases. American Journal of Clinical Pathology.28: 56-63.The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered aspartate was added into all the test tubes. Then 0.05 ml of serum was added to the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37^{o}C for 60 min, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution I was added to all test tubes. Mixed properly and optical density was measured in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:-

AST (GOT) activity in IU/L) = [(Absorbance of test - Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard

2. Determination of alanine aminotransferase (ALT)

Alanine aminotransferase, also known as Glutathione Peroxidase (GPT) catalyses the transamination of L-alanine and α keto glutarate to form pyruvate and L- Glutamate. Pyruvate so formed is coupled with 2,4 – Dinitrophenyl hydrazine to form a corresponding hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

Reagents

Buffered alanine (pH 7.4), 2,4–DNPH, 4N sodium hydroxide, working pyruvate standard, solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

Procedure

Rietman and Frankle method was dopted for the estimation of SGPT. The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered alanine was added into all the test tubes. This was followed by the addition of 0.05 ml of serum into the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37^{o}C for 60 minutes, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution **I** was added to all test tubes. Mixed properly and optical density was read against purified water in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:- ALT (GPT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard.

3. Determination of alkaline phosphatase (ALP)

Alkaline phoshatase from serum converts phenyl phosphate to inorganic phosphate and phenol at pH 10.0. Phenol so formed reacts in alkaline medium with 4-aminoantipyrine in presence of the oxidising agent potassium ferricyanide and forms an orange-red coloured complex, which can be measured spectrometrically. The color intensity is proportional to the enzyme activity.

Reagents:

Buffered substrate

Chromogen Reagent

Phenol Standard, 10 mg%

Procedure:

ALP was determined using the method of Kind (Kind PRM, King EJ, 1972. *In-vitro* determination of serum alkaline phosphatase. Journal of Clinical Pathology 7: 321-22\). The working solution was prepared by reconstituting one vial of buffered substrate with 2.2 ml of water. 0.5 ml of working buffered substrate and 1.5 ml of purified water was dispensed to blank, standard, control and test. Mixed well and incubated at 37^0C for 3 min. 0.05 ml each of serum and phenol standard were added to test and standard test tubes respectively. Mixed well and incubated for 15 min at 37^0C. Thereafter, 1 ml of chromogen reagent was added to all the test tubes. Then, added 0.05 ml of serum to control. Mixed well after addition of each reagent and the O.D of blank, standard, control and test were read against purified water at 510 nm.

Serum alkaline phosphatase activity in KA units was calculated as follows
[(O.D. Test-O.D. Control) / (O.D. Standard- O.D. Blank)] x 10

4. Determination of bilirubin

In toxic liver, bilirubin levels are elevated. Hyperbilirubinemia can result from impaired hepatic uptake of unconjugated bilirubin, such a situation can occur in generalized liver cell injury, certain drugs (e.g Rifampin and probenecid) interfere with the rat uptake of bilirubin by the liver cell and may produce a mild unconjugated hyperbilirubinemia. Bilirubin level rises in diseases of hepatocytes, obstruction to bilirubin excretion into duodenum, in haemolysis and defects of hepatic uptake and conjugation of Bilirubin pigment such as Gilbert's disease.

Elevation of total serum bilirubin may occur due to:

1.Excessive haemolysis or destruction of the red blood cells.Eg:Haemolytic disease of the new born.

2.Liver diseases.Eg.Hepatitis and cirrhosis.

3.Obstruction of the biliary tract.Eg.Gall stones.

The method is based on the reaction of Sulfonilic acid with sodium nitrite to form azobilirubin which has maximum absorbance at 546nm in the aqueous solution. The intensity

of the color Produced is directly proportional to the amount of direct or total bilurubin concentration present in the sample.

Reagents

1. Diazo A-(Reagent-R1) :Ready to use
2. Diazo B-(Reagent-R2):Ready to use
3. Bilirubin Activater :Ready to use

Procedure

Kind & King's method was followed for the estimation of Bilirubin. Five hundred µl of working reagent was added to 50 µl of rat serum & incubated for 5 min at 37°C. Absorbance was measured AT 546 NM in semi auto analyzer against the standard.

The Bilirubin content was calculated using the following equation:

Total bilirubin (mg/dt) = Abs of the sample blank x 15.

Direct Bilirubin(mg/dt) = Abs of sample blank x 10.

5. ESTIMATION OF UREA

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyper uremia or azotemia.

Method

Estimation of urea was done by Urease-GLDH: enzymatic UV test.

Principle

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4 + 2HCO_3$$

$$\text{2- Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L- Glutamate} + NAD^+ + H_2O$$

Table 14. Reagents

R 1	TRIS pH 7.8	120 mmol/l
	2-Oxoglutarate	7 mmol/l
	ADP	0.6 mmol/l
	Urease	≥ 6 KU/l
	GLDH	≥ 1 KU/l

R 2	NADH	0.25 mmol
R 3	Standard	40 mg/dl

Procedure

a. Take 1000 µl of reagent-1 and 250 µl of reagent-2 in 5 ml test tube.
b. To this, add 10 µl of serum.
c. Mix well and immediately read the test sample at 340 nm Hg 334 nm Hg 365 nm optical path 1 cm against reagent blank (2-point kinetic).
d. And note down the value.

Normal range: 10 – 50 mg/dl.

6. ESTIMATION OF URIC ACID

Uric acid and its salts are end products of the purine metabolism. In gout the most common complication of hyperuricemia, ie. Increased serum levels of uric acid lead to formation of monosodium urate crystal around the joints.

Method

Enzymatic photometric test using TOOS (N ethyl- N (hydroxyl -3- sulfopropyl)-m- toluidin)

Principle

Uric acid + H_2O + O_2 $\xrightarrow{\text{uricase}}$ Allantoin +CO_2 +H_2O_2

TOOS + 4 aminoantipyrine + $2H_2O_2$ $\xrightarrow{\text{POD}}$ Indamine + $3H_2O$

Table 15.reagents

R1	Phosphate buffer pH 7.0	100mmol/l
	TOOS	1mmol/l
	Ascorbate oxidase	≥1 KU/l
R2	Phosphate buffer pH 7.0	100mmol/l
	4- amino antipyrine	0.3mmol/l
	K_4 (Fe(CN)$_6$)	10µmol/l
	Peroxidase	≥1KU/l
	Uricase	≥50U/l

Procedure

a. Take 800µl of reagents -1 in a2ml centrifuge tube.
b. To this add 20µl of serum.
c. Mix well and incubate at 30°c for 5 minutes.
d. Then add 200µl of reagent2
e. Mix well incubate for 5min at 37°c
f. Measure the not down the values.

Normal range: 1.9-8.2mg/dl

7. ESTIMATION OF CREATININE:

Principle:

Creatinine forms a coloured complex with picrate in alkaline medium.

The rate of formation of the complex is measured.

Reagents:

Reagent 1 Standard Creatinine (2mg/100ml)

Reagent 2 Picric acid solution.

Reagent 3 sodium hydroxide solution

Procedure:

Take 500 µl of reagent -2 and 500 µl of reagent -3 in a 5ml test tube. To this add 100 µl of serum. Mix well and immediately read the test sample at Hg 492 nm 1cm light path and note down the values.

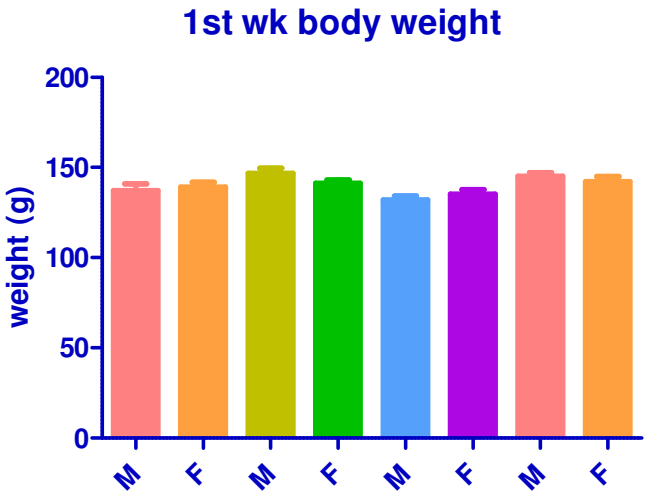
Normal range is 0.6 -1.1 mg/dl.

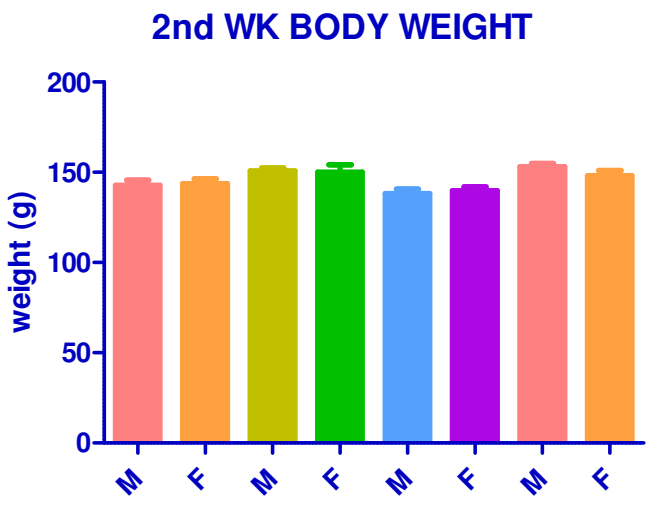
TABLE: 1 EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BODY WEIGHT IN Gram (PHYSICAL PARAMETER)

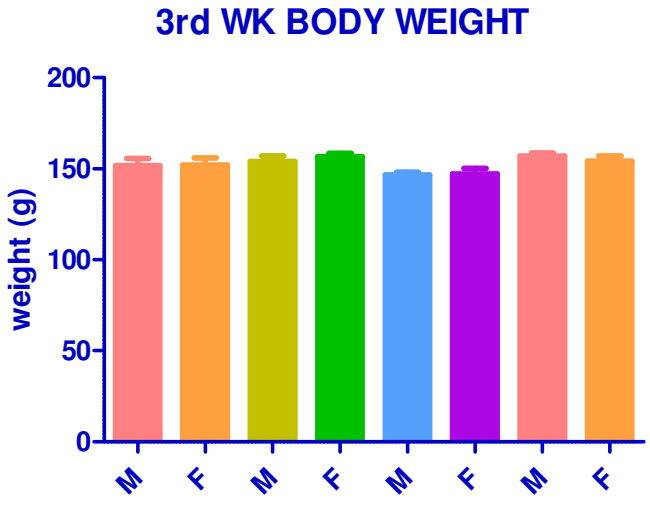
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BODY WEIGHT IN Gram (PHYSICAL PARAMETER).

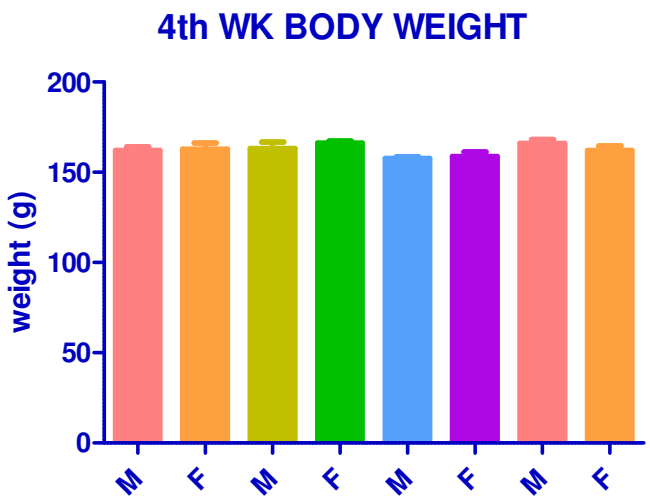
GPs	Control		Low Dose		Middle Dose		High Dose	
	Male	Female	Male	Female	Male	Female	Male	Female
1st wk	137.3±3.528	139.3±2.404	146.7±2.906	141.3±1.764	132±2.309	135.3±2.404	145.3±1.764	142.3±2.728
2nd wk	142.7±2.906	143.7±2.603	150.7±1.764	150±4.163	138±2.646	139.7±2.186	153±1.732	148±2.887
3rd wk	151.7±3.844	152±4	154±3.055	156.7±1.764	146.7±1.453	147.3±2.963	157±1.528	154.3±2.728
4th wk	162±2.082	162.7±3.528	163.3±3.48	166.3±0.8819	157.7±0.8819	158.7±2.603	166±2.082	162±2.646

Values are expressed as the mean ± S.D




2nd WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F


3rd WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F



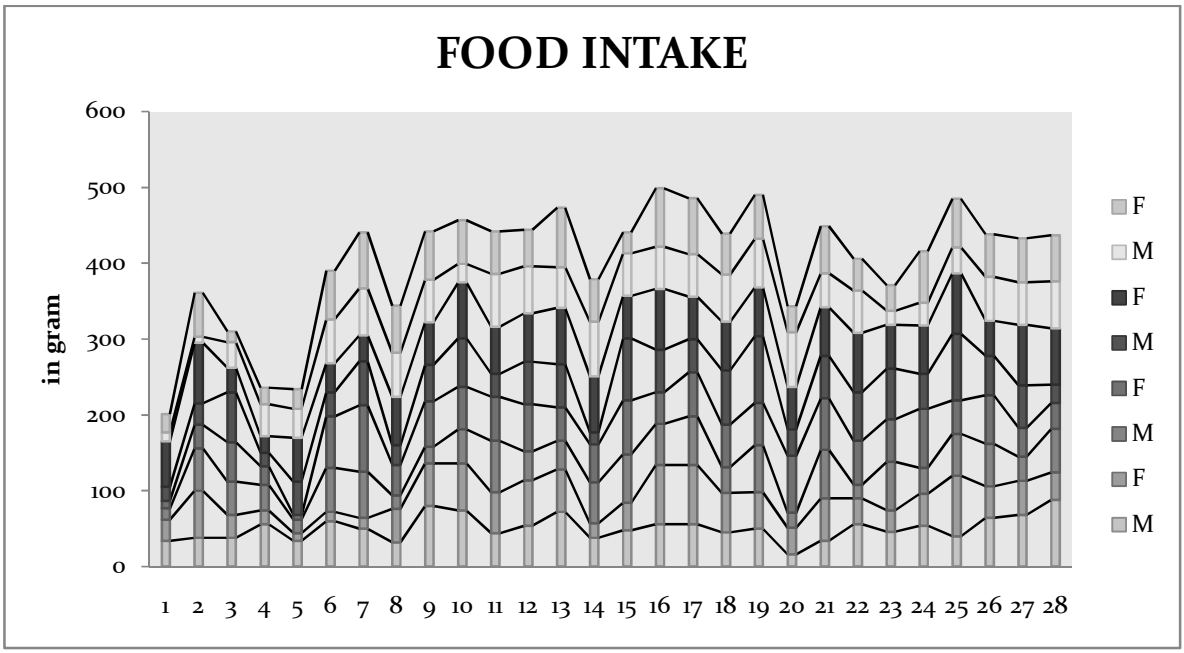
EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON FOOD INTAKE In Gram

Effect Of Sub Acute Doses (28 Days) 0f VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON FOOD INTAKE IN Gram

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	34	28	15	10	18	60	12	24
DAY2	38	62	56	31	28	80	8	58
DAY3	38	30	44	52	66	32	34	14
Day 4	56	18	34	24	18	22	42	22
DAY5	34	10	18	6	44	58	38	26
Day 6	60	12	58	68	32	38	58	64
DAY7	50	14	61	88	58	34	62	74
DAY8	32	44	18	40	26	64	58	62
Day 9	80	56	22	60	48	56	56	64
DAY10	74	62	45	56	64	74	24	58
Day 11	44	54	68	58	30	62	70	56

DAY12	54	60	38	62	56	64	62	48
DAY13	72	56	38	44	57	74	54	78
Day 14	38	19	54	50	16	74	72	56
DAY15	48	36	64	71	82	56	56	28
Day 16	56	78	54	42	56	80	56	77
DAY17	56	78	64	58	44	56	56	74
DAY18	45	52	34	56	72	64	62	54
Day 19	50	48	62	56	88	64	64	58
DAY20	16	35	20	75	35	56	72	34
DAY21	34	56	64	68	56	64	45	62
Day 22	56	34	18	58	64	78	56	42
DAY23	46	28	64	56	67	58	18	34
DAY24	54	42	34	78	46	64	30	68
Day 25	40	80	55	44	88	80	34	64
DAY26	64	42	56	64	52	46	58	56
DAY27	68	45	32	38	56	80	56	58
DAY28	88	36	58	34	24	74	62	61

Values are expressed as the mean ± S.D


FOOD INTAKE
in gram
600
500
400
300
200
100
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28
F
M
F
M
F
M
F
M

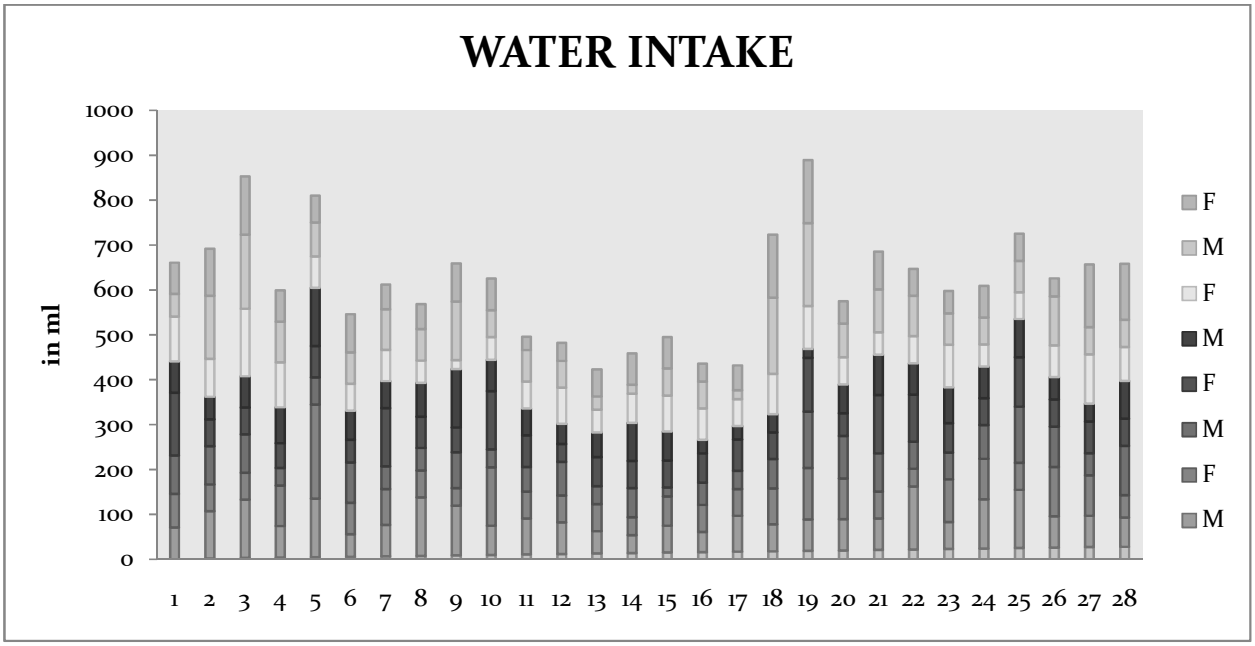
EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON WATER INTAKE IN ml

Effect Of Sub Acute Doses (28 Day) 0f VATHATHIRKU LEGHIYAM WITH HONEY/GHEE on Water Intake in ml

Groups	Control		Low Dose		Middle Dose		High Dose	
DAY	Male	Female	Male	Female	Male	Female	Male	Female
Day 1	70	75	85	140	70	100	50	70
DAY2	105	60	85	60	50	85	140	105
DAY3	130	60	85	60	70	150	165	130
Day 4	70	90	40	55	80	100	90	70
DAY5	130	210	60	70	130	70	75	60
Day 6	50	70	90	50	65	60	70	85
DAY7	70	80	50	130	60	70	90	55
DAY8	130	60	50	70	75	50	70	55
Day 9	110	40	80	55	130	20	130	85
DAY10	65	130	40	130	70	50	60	70
Day 11	80	60	55	70	60	60	70	30
DAY12	70	60	75	40	45	80	60	40
DAY13	50	60	40	65	55	50	30	60
Day 14	40	40	65	60	85	65	20	70
DAY15	60	65	20	60	65	80	60	70
Day 16	45	60	50	65	30	70	60	40
DAY17	80	60	40	70	30	60	20	55
DAY18	60	80	65	60	40	90	170	140

Day 19	70	115	125	120	20	95	185	140
DAY20	70	90	95	50	65	60	75	50
DAY21	70	60	85	130	90	50	95	85
Day 22	140	40	60	105	70	60	90	60
DAY23	60	95	60	65	80	95	70	50
DAY24	110	90	75	60	70	50	60	70
Day 25	130	60	125	110	85	60	70	60
DAY26	70	110	90	60	50	70	110	40
DAY27	70	90	50	70	40	110	60	140
DAY28	65	50	110	60	85	75	60	125

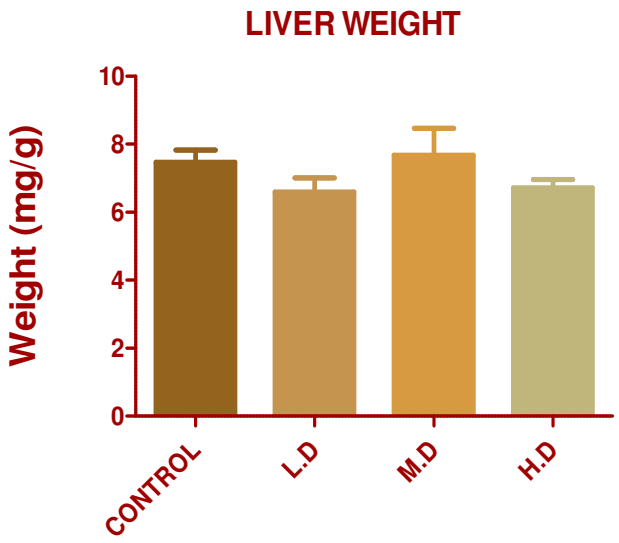
Values are expressed as the mean ± S.D

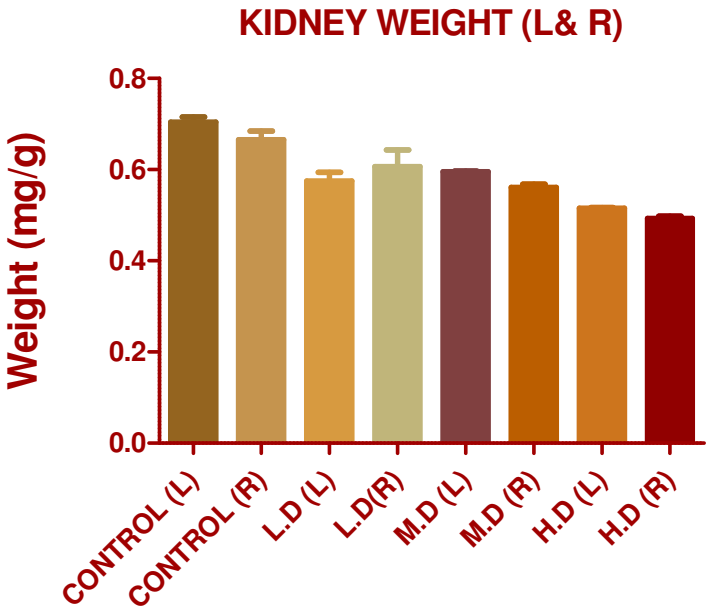


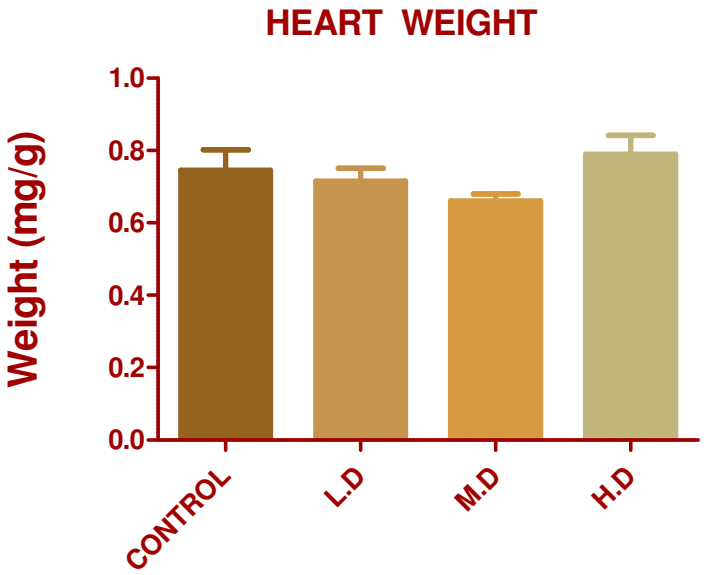
EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON ORGAN WEIGHT in gm

GROUP		CONTROL	Low Dose	Middle Dose	High Dose
LIVER WEIGHT		7.472±0.356	6.59±0.415^{ns}	7.678±0.788^{ns}	6.721±0.241^{ns}
KIDNEY WEIGHT	L	0.704±0.0114	0.574±0.019**	0.596±0.00145*	0.515±0.0018***
	R	0.666±0.0180	0.607±0.0354	0.560±0.0078**	0.493±0.0043***
HEART WEIGHT		0.745±0.0565	0.715±0.0343	0.660±0.0190	0.79±0.0517
LUNGS WEIGHT		1.728±0.122^{ns}	1.33±0.0596^{ns}	1.663±0.1328^{ns}	1.627±0.03301^{ns}
TESTIS WEIGH		2.357±0.01615	2.281±0.07202	1.739±0.1249*	1.89±0.179
		0.6793±0.0594	0.605±0.04431	0.5553±0.06623	0.5967±0.03567

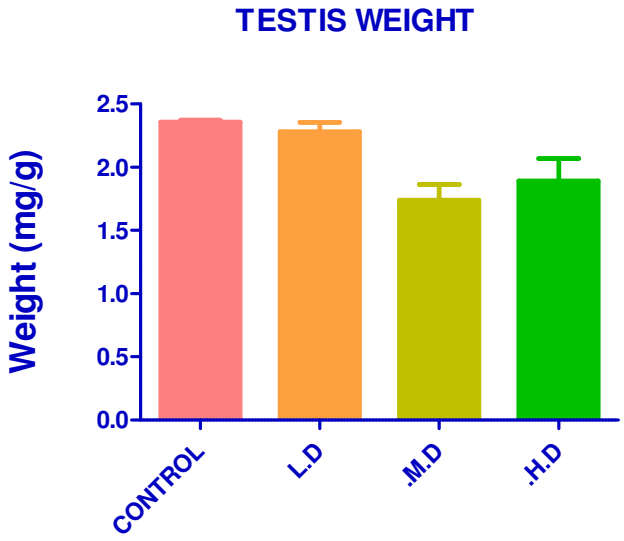
Values arae expressed as mean ± SEM Statistical significance (p) calculated by one way ANOVA followed by dunnett's (n=6); ^{ns}p>0.05, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group.

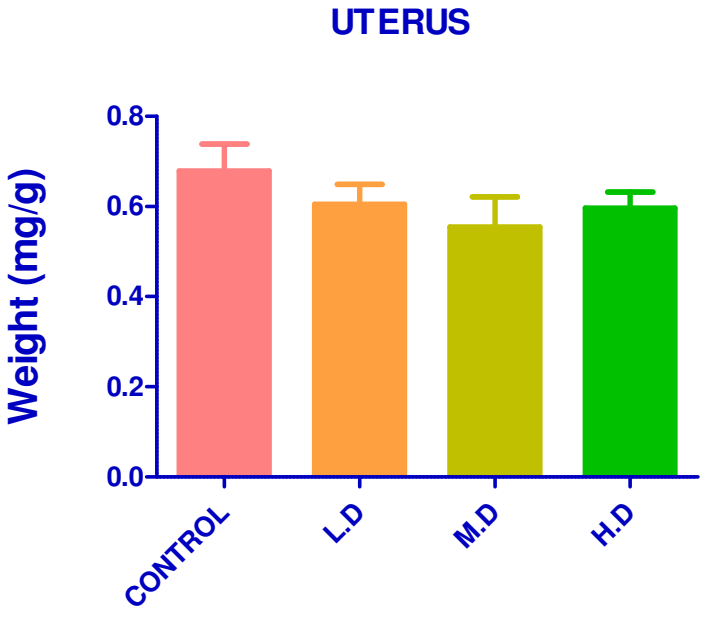

LIVER WEIGHT
Weight (mg/g)
10
8
6
4
2
0
CONTROL
L.D
M.D
H.D


KIDNEY WEIGHT (L& R)
Weight (mg/g)
0.8
0.6
0.4
0.2
0.0
CONTROL (L)
CONTROL (R)
L.D (L)
L.D(R)
M.D (L)
M.D (R)
H.D (L)
H.D (R)


HEART WEIGHT
Weight (mg/g)
1.0
0.8
0.6
0.4
0.2
0.0
CONTROL
L.D
M.D
H.D


LUNGS WEIGHT
Weight (mg/g)
2.0
1.5
1.0
0.5
0.0
CONTROL
L.D
M.D
H.D


TESTIS WEIGHT
Weight (mg/g)
2.5
2.0
1.5
1.0
0.5
0.0
CONTROL
L.D
.M.D
.H.D

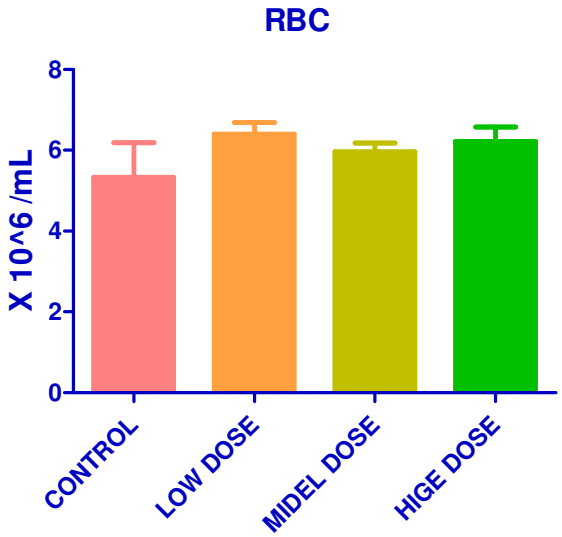

UTERUS
Weight (mg/g)
0.8
0.6
0.4
0.2
0.0
CONTROL
L.D
M.D
H.D

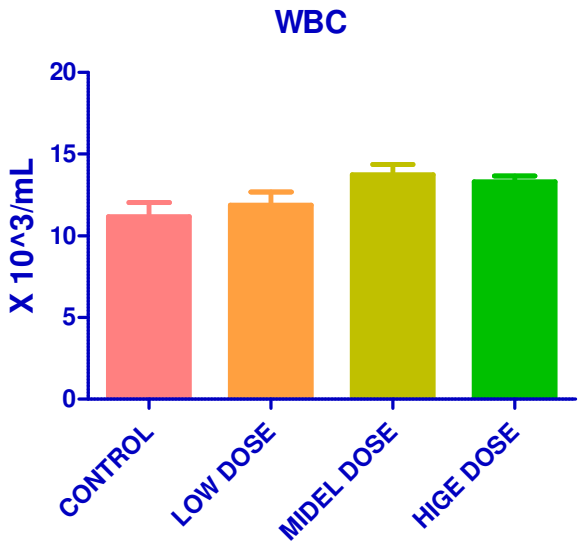
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON HAEMATOLOGICAL PARAMETERS

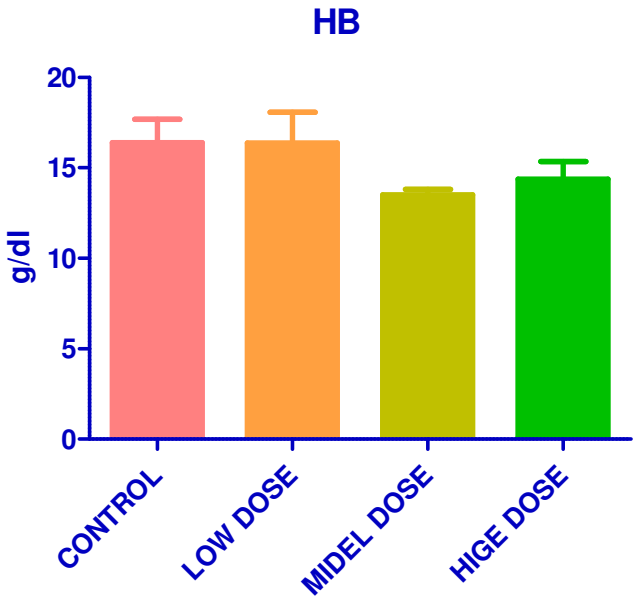
Effect Of Sub Acute Doses (28 Day) 0f Vathathirku Leghiyam With Honey/Ghee On Haematological Parameters

Groups	Control	Low Dose	Middle Dose	High Dose
Rbc ($X10^3/\mu l$)	5.33±0.8585	6.403±0.289	5.96±0.2173	6.213±0.3619
Wbc($X10^6/\mu l$)	11.17±0.8762	11.87±0.8212	13.73±0.636	13.3±0.3606
Hb (g/dl)	16.4±1.29	16.37±1.707	13.5±0.3055	14.37±0.977

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



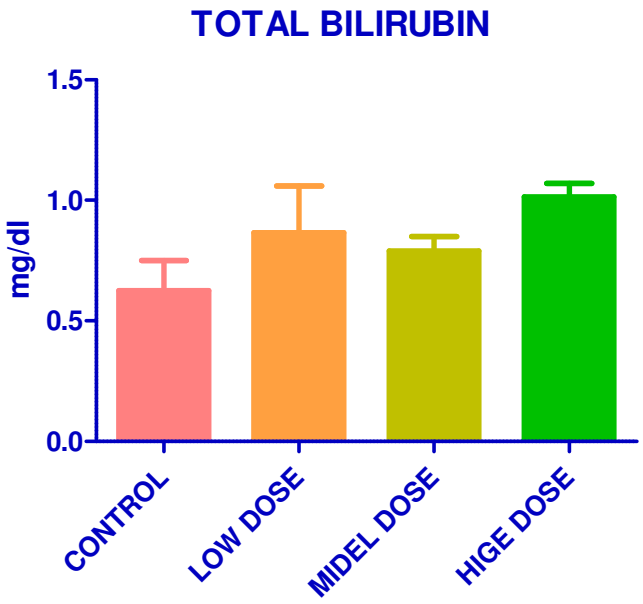

WBC
X 10^3/mL
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HB
g/dl
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total Bilirubin(mg/dl)	0.625±0.125	0.865±0.195	0.79±0.06	1.015±0.055

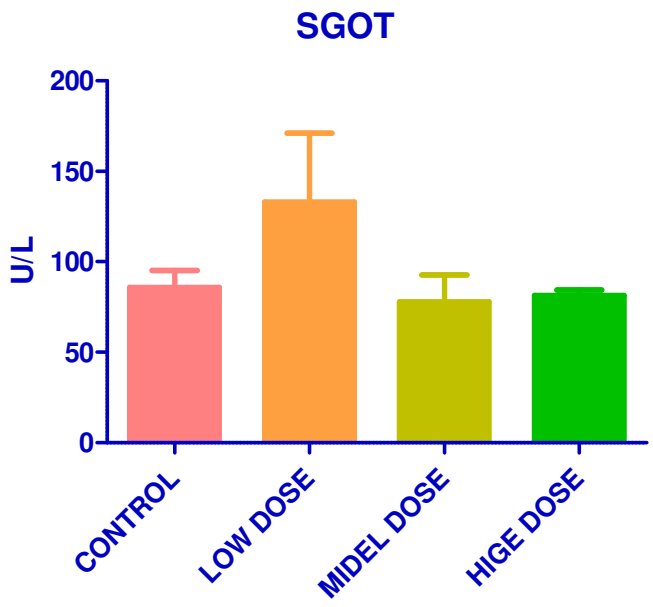
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.

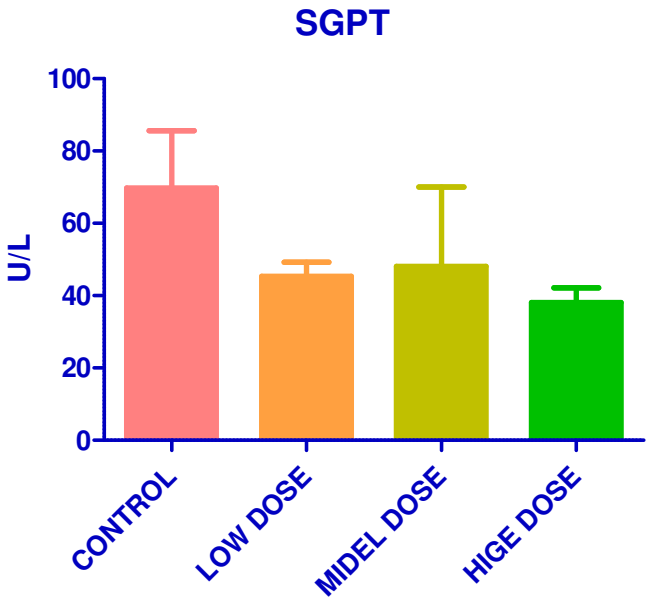


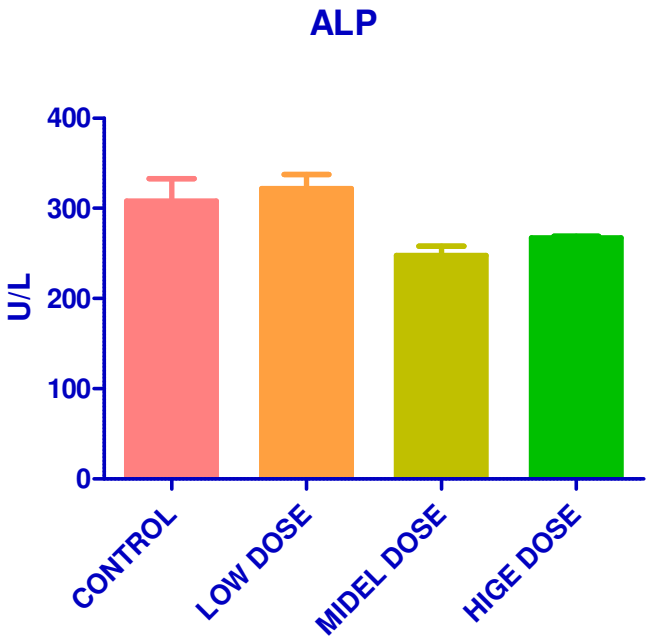
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIVER PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
SGOT (U/L)	85.95±9.25	133.2±37.95	77.9±14.9	81.35±3.05
SGPT (U/L)	69.79±15.72	45.4±3.8	48.15±21.85	38.15±3.95
ALP (U/L)	308.2±24.55	321.8±15.75	247.8±10.55	267.3±1.9

Values are expressed as the mean ± S.D; Statistical significance (p) calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



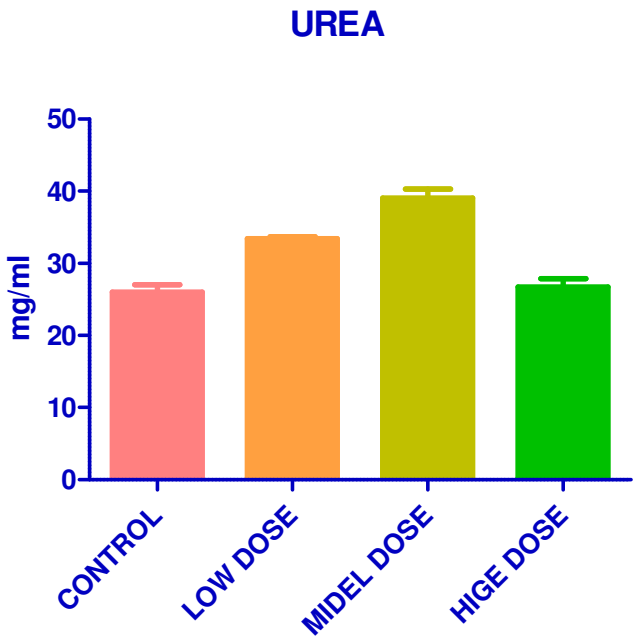

SGPT
100
80
60
40
20
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


ALP
400
300
200
100
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

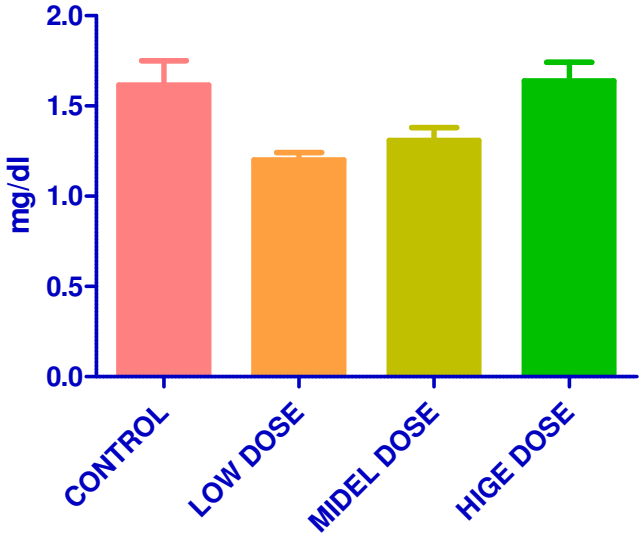
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (KIDNEY PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Urea (mg/dl)	26.03±1.01	33.45±0.25	39.08±1.18	26.74±1.13
Uric acid (mg/dl)	1.615±0.135	1.2±0.04	1.31±0.07	1.64±0.1
Creatinine (mg/dl)	0.33±0.05	0.275±0.005	0.23±0.02	0.29±0.09

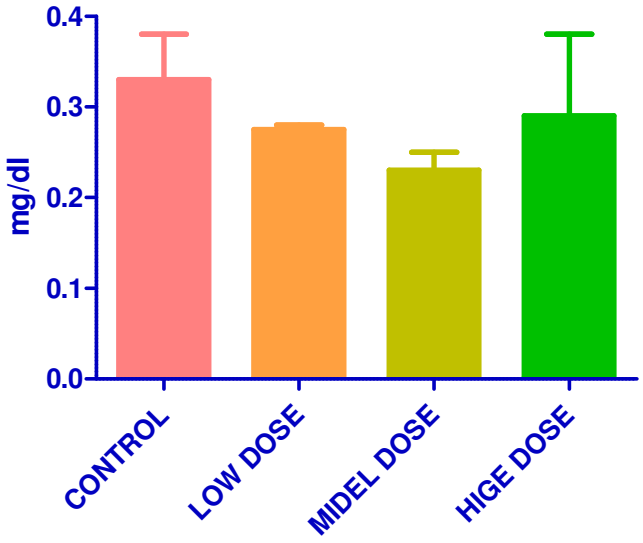
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



URIC ACID



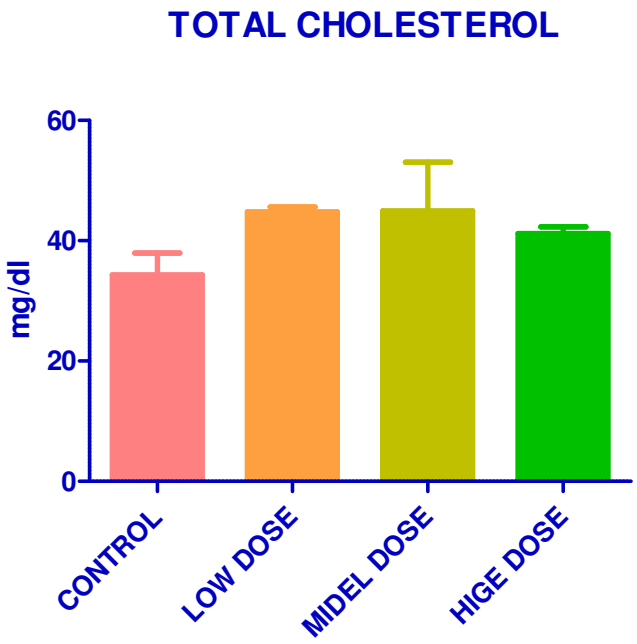
CREATININE

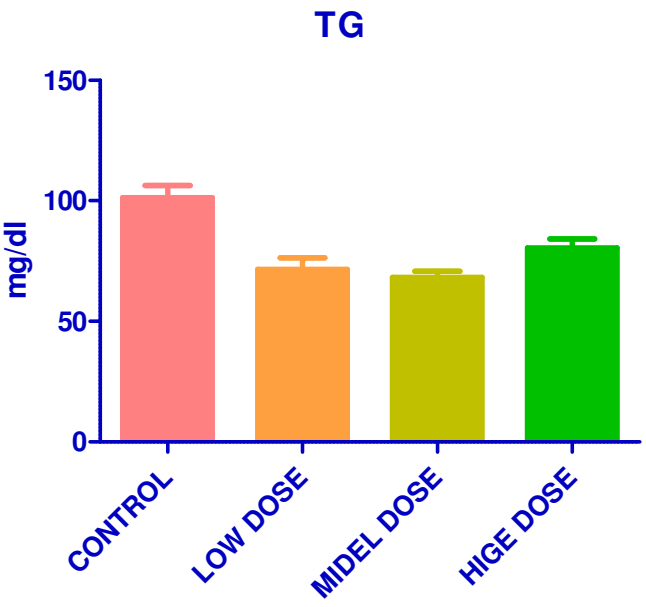


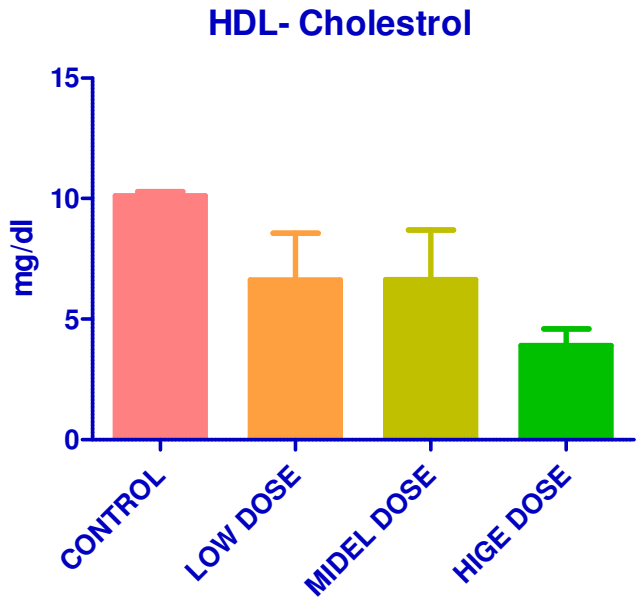
EFFECT OF SUB ACUTE DOSES (28 DAY) 0F VATHATHIRKU LEGHIYAM WITH HONEY/GHEE ON BIOCHEMICAL PARAMETER (LIPID PROFILE)

Groups	Control	Low Dose	Middle Dose	High Dose
Total cholesterol (mg/dl)	34.3±3.6	44.85±0.75	44.95±8.05	41.2±1.1
Triglycerides (mg/dl)	101.3±5	71.55±4.85	68.28±2.48	80.4±3.8
HDL-Cholesterol (mg/dl)	10.12±0.185	6.625±1.945	6.65±2.05	3.9±0.7

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.




TG
150
100
50
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HDL- Cholestrol
15
10
5
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

RESULTS:

CLINICAL SIGNS:

All animals in this study were free of toxic clinical signs throughout the dosing period of 28 days.

Mortality:

All animals in control and in all the treated dose groups survived throughout the dosing period of 28 days.

Body weight:

Results of body weight determination of animals Table-1 from control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days.

Food consumption:

During dosing and the post-dosing recovery period, the quantity of food consumed by animals from different dose groups was found to be comparable with that by control animals.

Organ Weight:

Group Mean Relative Organ Weights (% of body weight) are recorded in Table No.4 Comparison of organ weights of treated animals with respective control animals on day 29 was found to be comparable similarly.

Hematological investigations:

The results of hematological investigations (Table 4) conducted on day 29 revealed following significant changes in the values of different parameters investigated when compared with those of respective controls; however, the increase or decrease in the values obtained was within normal biological and laboratory limits or the effect was not dose dependent.

Biochemical Investigations:

Results of Biochemical investigations conducted on days 29 and recorded in Table 2 revealed the following significant changes in the values of hepatic

serum enzymes studied. When compared with those of respective control. However, the increase or decrease in the values obtained was within normal biological and laboratory limits.

Histopathology:

In histopathological examination, revealed normal architecture in comparison with control and treated animal.

DISCUSSION:

1) All the animals from control and all the treated dose groups up to 500 mg/kg survived throughout the dosing period of 28 days.

2) No signs of toxicity were observed in animals from different dose groups during the dosing period of 28 days.

3) Animals from all the treated dose groups exhibited comparable body weight gain with that of controls throughout the dosing period of 28 days.

4) Food consumption of control and treated animals was found to be comparable throughout the dosing period of 28 days

5) Haematological analysis conducted at the end of the dosing period on day 29, revealed no abnormalities attributable to the treatment.

6) Biochemical analysis conducted at the end of the dosing period on day 29 no abnormalities attributable to the treatment.

7) Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable with that of respective controls.

8) Histopathological examination revealed normal architecture in comparison with control and treated animal.

SUMMARY AND CONCLUSION:

In conclusion **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE** can be considered safe, as it did not cause either any lethality or adverse changes with general behavior of rats and also there were no observable detrimental effects (100 to 300 mg/kg body weight) over a period of 28 days.

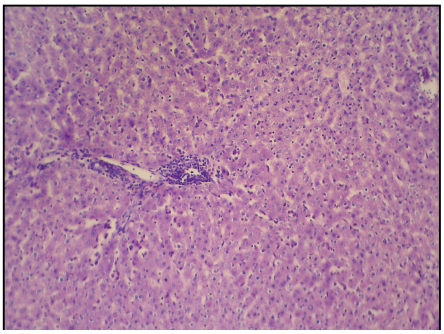
Our results have demonstrated that the **VATHATHIRKU LEGHIYAM WITH HONEY/GHEE** is relatively safe when administered orally in rats.

9.0 ABBRVIATION

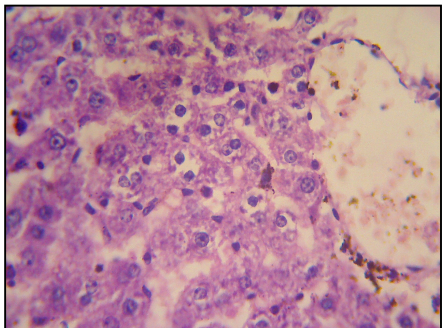
No.	Number
Mg	Milligram
Kg	Kilogram
LD_{50}	Lethal Dose $_{50}$
p.o.	peros
mL	Milliliter
%	percentage
R&D	Research and Development
EDTA	Ethylene Diamine Tetra Acetic Acid
M	Male
g%	Gram percentage
g	Gram
NOAEL	No-Observed-Adverse-Effect-Level
MLD	Minimum Lethal Dose
MTD	Maximum Tolerated Dose
OECD	Organisation of Economic Co-operation and Development
CPCSEA	Committee for the Purpose of Control and Supervision of Experiments on Animals

HISTOPATHOLOGY - TOXICITY STUDY

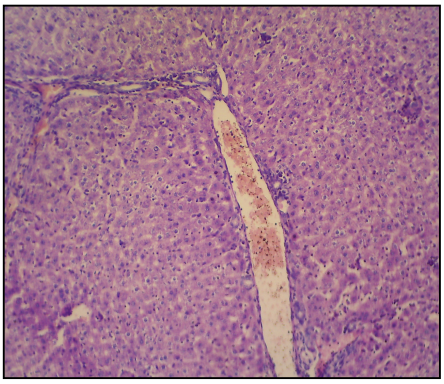
SPECIMEN : A) Liver. Group – : Vathathirkku leghiyam.



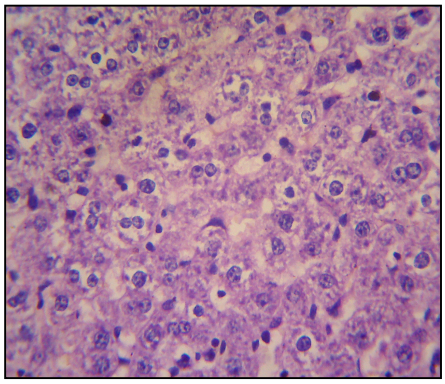
10x shows mild alterd architecture



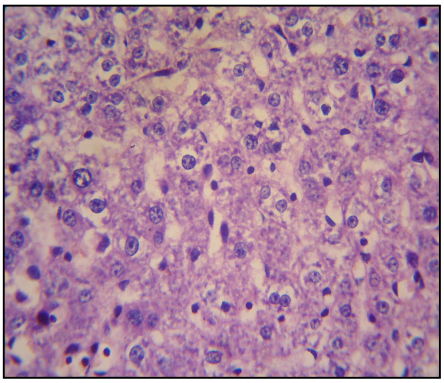
40x shows central vein congestion (2)



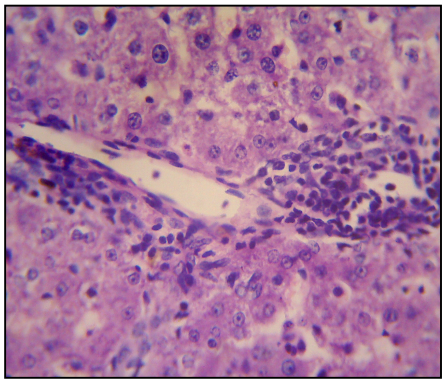
40x shows central vein congestion



40x shows reactive atypia



40x shows interface hepatitis and kuffer cell



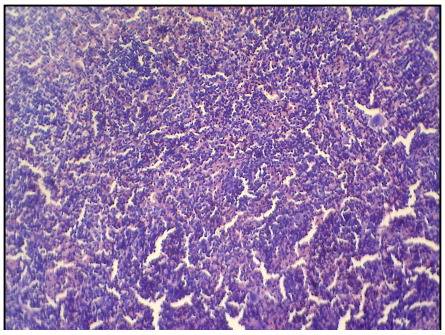
40X shows mild periportal inflammation

MICROSCOPIC APPEARANCE:

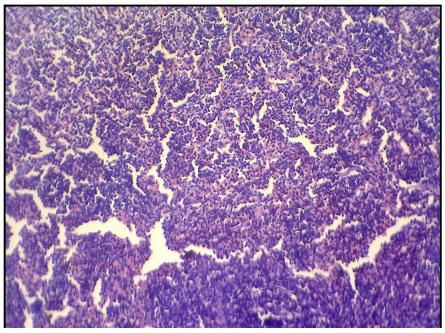
Section from liver shows lobular architecture with interface hepatitis. Individual Hepatocytes shows reactive atypia. Portal triad shows no significant pathology. Central vein and Sinusoids show dilatation.

SPECIMEN : B) spleen.

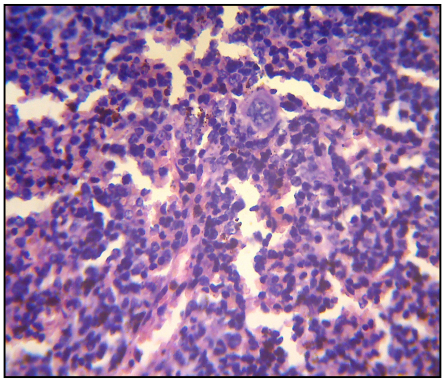
Group – : Vathathirkku leghiyam



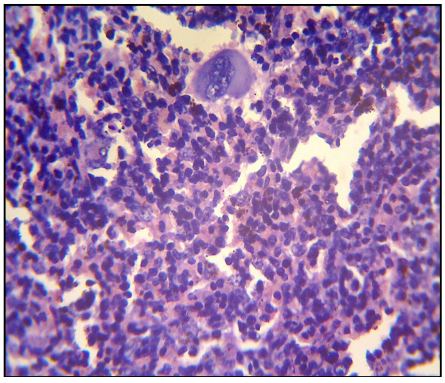
10x shows normal spleen with megakaryocytes



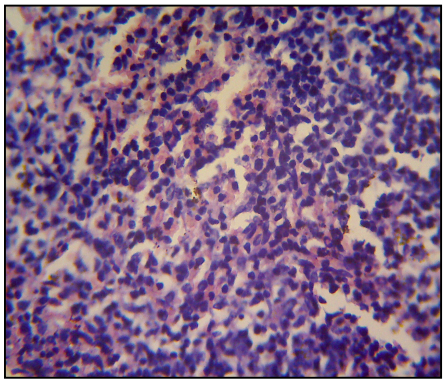
10x shows spleen with normal red and white pulp



40x shows megakaryocytes



40x shows normal white pulp with megakaryocytes



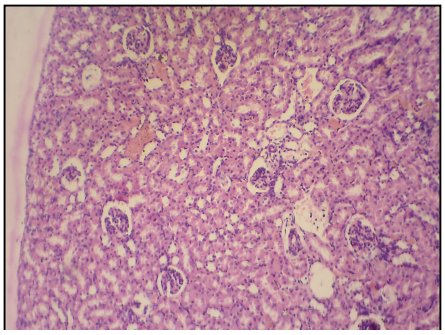
40x showws white pulp and red pulp

MICROSCOPIC APPEARANCE:

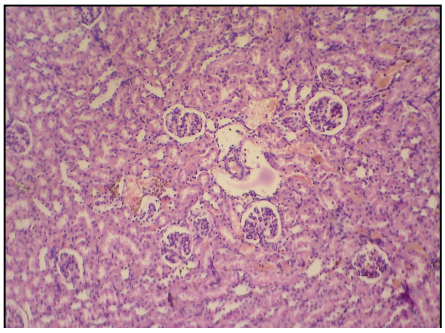
Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. Megakaryocytes

SPECIMEN : C) Kidney.

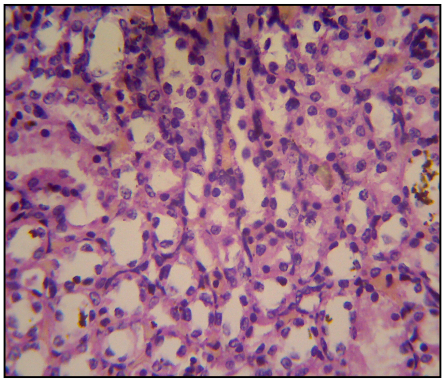
Group – : Vathathirkku leghiyam



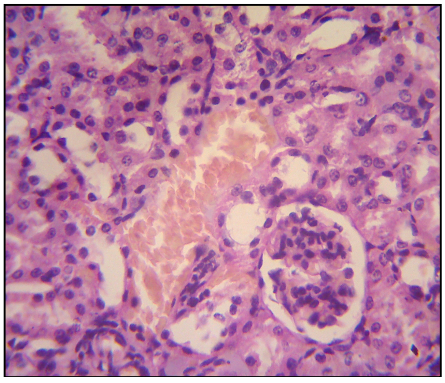
10x shows both cortex and medulla



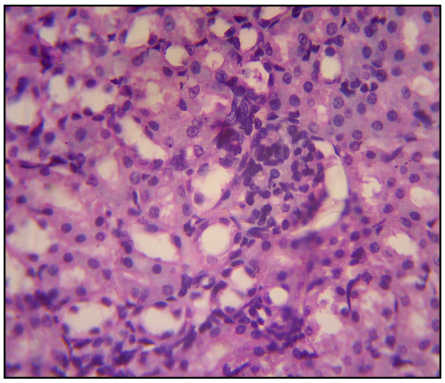
10x shows normal kidney



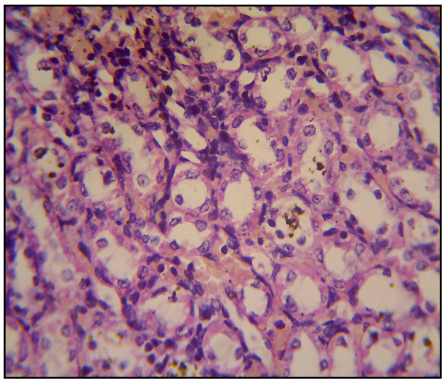
40 shows tubules



40x shows focal segmental glomerulo nephritis with blood vessels congestion



40x shows glomeruli and tubules



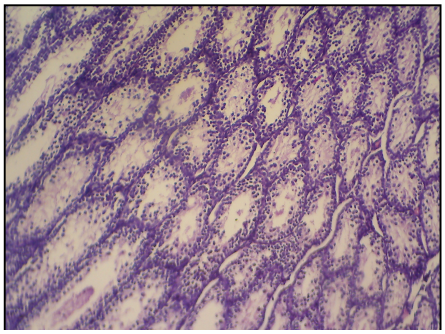
40x shows normal tubules

MICROSCOPIC APPEARANCE:

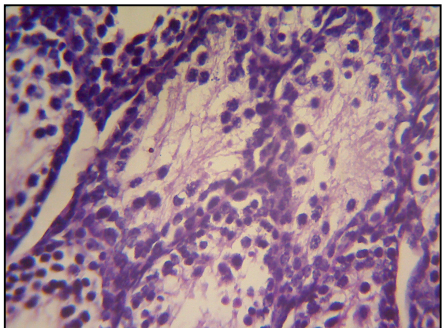
Section from kidney shows both cortex and medulla. Glomeruli and tubules shows no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion. There is no evidence of toxic changes.

SPECIMEN : D) Testis

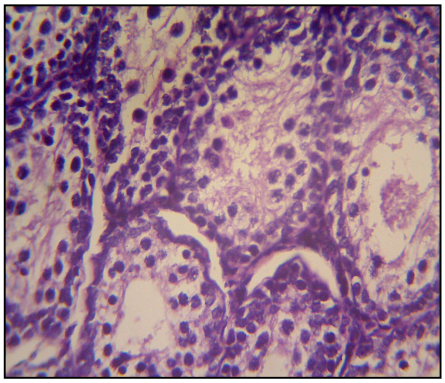
Group – : Vathathirkku leghiyam



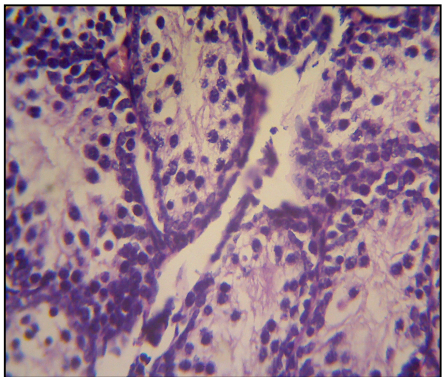
10 shows normal spermatogenesis



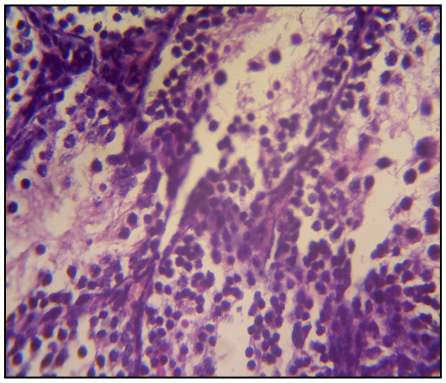
40x shows normal seminiferous tubules



40x shows normal spermatogenesis with normal maturation (2)



40x shows normal spermatogenesis with normal maturation



40x

MICROSCOPIC APPEARANCE:

Section from testes with seminiferous tubules showing maturation arrest with lacking of spermatogenesis.

ANNEXURE –V

ASSESSMENT FORMS

FORM I **:** Screening and Selection Proforma

FORM I A **:** History Proforma on Enrollment

FORM II : Clinical assessment on enrollment

FORM II A **:** Clinical assessment during and after trial

FORM III : Laboratory Investigation on enrollment and conclusion of trial

FORM IV : Consent Form

FORM IV B : Withdrawal form

FORM IV C : Patient information sheet

FORM IV D : Dietary Advice form

FORM IV E : Adverse Reaction form

FORM IV F : Discharge proforma

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL

POST GRADUATE DEPARTMENT

PALAYAMKOTTAI, TIRUNELVELI – 627002

BRANCH – III SIRAPPU MARUTHUVAM

A PILOT STUDY TO EVALUATE THE THERAPEUTIC EFFICACY OF SIDDHA FORMULATION "**VATHATHIRKU LEGHIYAM**" INTERNAL & "**PANCHARKA THYLAM**" EXTERNAL IN "**CEGANAVATHAM**" (CERVICAL SPONDYLOSIS).

FORM I – SCREENING & SELECTION PROFORMA

1. OP / IP NO : _____
2. NAME : _____
3. RELIGION : H / C / M / O
4. AGE / GENDER : _____
5. OCCUPATION : _____
6. INCOME : _____
7. CONTACT NO : _____
8. INCLUSION CRITERIA :

INCLUSION CRITERIA:

Age : Between 20 years and 60 years

Sex : Male and female

- Pain, stiffness and restricted movements in the neck.

- Tingling sensation, numbness in the upper limbs.
- Radiating pain in the upper limbs.
- Feeling of heaviness in the body and weakness of the limb
- Constipation
- Mental depression
- Burning sensation of eyes.

EXCLUSION CRITERIA:

- Cervical rib
- Trauma
- Spina bifida
- Diabetes mellitus
- Ankylosing spondylosis
- Tuberculosis in spine
- Cardiac disease
- Pregnancy and lactation
- Neoplasms
- Patients with any other serious systemic illness
- Congenital anomalies of spine.

ADMITTED TO TRIAL:

YES NO

If Yes Serial Number :

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL

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FORM I A – HISTORY PROFORMA

1. SL.NO : _____
2. OP / IP NO : _____
3. NAME : _____
4. RELIGION : H / C / M / O
5. AGE / GENDER : _____
6. OCCUPATION : _____
7. INCOME : _____
8. CONTACT NUMBER : _____
9. MARITAL STATUS : Married / Unmarried
10. COMPLAINTS & DURATION :

11. PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION
Smoking			
Tobacco Chewing			
Alcohol			
Narcotic Drug Addiction			

12. DRUG HISTORY:

Whether the Patient has underwent any allopathic Treatment

1. Yes 2. No.

If yes specify the nature of the drug and treatment duration _____

13. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2. No

If yes, mention the relationship of affected person(s)

1. _____
2. _____

14. DIETARY HABITS :

1. Pure vegetarian ☐
2. Non-Vegetarian ☐

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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BRANCH – III SIRAPPU MARUTHUVAM

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FORM II AND II-A CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS

1.	OP / IP No	:
2.	BED No	:
3.	SL. NO	:
4.	NAME	:
5.	AGE	:
6.	GENDER	:
7.	OCCUPATION	:
8.	SOCIAL STATUS	:
9.	DATE OF ADMISSION	:
10.	DATE OF DISCHARGE	:
11.	POSTAL ADDRESS	:
12.	COMPLAINTS & DURATION	:
13.	HISTORY OF PRESENT ILLNESS	:
14.	PAST HISTORY	:
15.	FAMILY HISTORY	:

16. MENSTRUAL HISTORY (If Applicable):

17. HABITS:

1. Smoker :
2. Alcoholic :
3. Tobbaco chewer :
4. Betel nut chewer :
5. Non-Vegetarian :
6. Drug addiction :

18. GENERAL EXAMINATION:

1. Body weight (Kg) :
2. Height (Cm) :
3. Body Temperature (F) :
4. Blood Pressure (mmHg) :
5. Pulse Rate (/min) :
6. Heart Rate (/min) :
7. Respiratory Rate (/min) :
8. Pallor :
9. Jaundice :
10. Clubbing :
11. Cyanosis :
12. Pedal Oedema :
13. Lymphadenopathy :
14. Jugular venous pulsation :

19. CLINICAL EXAMINATION:

I. INSPECTION:

1. Attitude :
2. Muscular spasm :
3. Muscle wasting – Proximal :
4. Muscle wasting – Distal :
5. Minor Joint Swelling :
6. Major Joint Swelling :
7. Nodules :
8. Deformity :

II. PALPATION:

1. Swelling :
2. Tenderness :
3. Joint Stiffness :
4. Muscle wasting :
5. Local heat :
6. Local Lymphadenopathy :
7. Pitting Oedema :
8. Nodules :

III. MOVEMENTS:

Restriction of joint movements

1.	Neck	:	Full	Partial
2.	Shoulder	:		
3.	Elbow joint	:		
4.	Knee joint	:		
5.	Ankle joint	:		
6.	Hip joint	:		
7.	Minor joints	:		

IV. PAIN:

1.	Onset :	Sudden	:	Gradual	:	
2.	Early morning stiffness :	Present	:	absent	:	
3.	Nature of pain:	Mild	:	Moderate	:	Severe:
4.	Aggravating factor –Movements		:			
5.	Relieving factor – rest		:			
6.	Stiffness		:			
7.	Tenderness		:			

V. CLINICAL ASSESSMENT :

1. Arthritis of three or more Joints :
2. Arthritis of hand joints :
3. Morning Stiffness :
4. Fever :
5. Anorexia :
6. Anaemia :
7. Spindle appearance of fingers :
8. Restricted movements :
9. Rheumatoid Nodules :
10. Numbness :

20. EXAMINATION OF OTHER SYSTEMS:

1. CVS :
2. RS :
3. CNS :
4. ABDOMEN :
5. GENITO – URINARY :

EXAMINATION – SIDDHA ASPECTS

1. NILAM:

1. Kurinji 2. Mullai 3. Marutham 4. Neithal 5. Paalai

2. KAALAM:

1. Kaar Kaalam 2. Koothir Kaalam 3. Munpani Kaalam
4. Pinpani Kaalam 5. Elavenir Kaalam 6. Mudhuvenir Kaalam

3. YAAKKAI:

1. Vatham	2. Pitham	3. Kabam
4. Vathapitham	5. Pithavatham	6. Kabavatham
7. Vathakabam	8. Pithakabam	9. Kabapitham

4. GUNAM:

1. Sathuvam 2. Rasatham 3. Thamasam

5. KANMENDHIRIUM / KANMAVIDAYAM

1. Kai :
2. Kaal :
3. Vaai :
4. Eruvaai :
5. Karuvaai :

6. UYIR THATHUKKAL:

I. VATHAM:

1. Piraanan :
2. Abaanan :
3. Viyaanan :
4. Uthaanan :
5. Samaanan :
6. Naagan :
7. Koorman :
8. Kirukaran :
9. Devathathan :
10. Dhananjeyan :

II. PITHAM :

1. Analagam :
2. Ranjagam :
3. Saathagam :
4. Aalosagam :
5. Praasagam :

III. KABAM:

1. Avalambagam :
2. Kilethagam :
3. Pothagam :
4. Tharpagam :
5. Santhigam :

7. UDAL THAATHUKKAL:

1. Saaram :
2. Senneer :
3. Oon :
4. Kozhuppu :
5. Enbu :
6. Moolai :
7. Sukkilam / Suronitham:

8. ENVAGAI THERVUGAL:

1. Naadi :
2. Sparisam :
3. Naa :
4. Niram :
5. Mozhi :
6. Vizhi :
7. Malam :

   i. Niram: ii. Thanmai: iii. Irugal: iv.Ilagal:

8. Moothiram :

I. NEERKURI:

a. Niram :

b. Manam :

c. Edai :

d. Nurai :

e. Enjal :

II. NEIKURI:

Vatha Neer : Pittha Neer : Kaba Neer :

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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FORM III – LABORATORY INVESTIGATION

1. BLOOD:
   1. TC : (Cells / Cumm)
   2. DC (%) : N : L : M : E :
   3. ESR (mm) : ½ hr : 1 hr :
   4. Hb :
   5. Blood Sugar : a) Fasting : b) Post Prandial :
   6. Renal function tests:
      Blood Urea: Serum creatinine:
   7. Lipid profile :
      HDL: LDL: VLDL:
      Total Cholesterol : TGL :
   8. Liver Function tests:
      Serum Bilirubin : Total Direct Indirect

SPECIFIC INVESTIGATIONS

RA factor :

ASO titre :

C-Reactive Protein :

SGOT :

SGPT :

Serum albumin & globulin :

Total protein :

II. URINE:

1. Albumin :

2. Sugar :
3. Epithelial cells :
4. Pus cells :
5. Red blood cells :
6. Casts / Crystals :

III. MOTION:

1. Ova :
2. Cyst :
3. Occult blood :
4. Pus cells :

IV. X-RAY FINDINGS

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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FORM IV A – CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the patient.

Signature _____

Date _____

Name _____

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial of "VATHATHIRKU LEGHIYAM" (Internal drug) and "PANCHARKA THYLAM" (External drug) for the treatment of "CEGANA VATHAM" (CERVICAL SPONDYLOSIS)".

Place :

Date :

Signature :

Name :

Witness Signature:

Name :

அரசினர் சித்த மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை

பாளையங்கோட்டை

பட்டமேற்படிப்பு சிறப்பு மருத்துவத்துறை

"வாததிற்க்கு லேகியம்" மற்றும் "பஞ்சார்க்கத் தைலம்" இவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : கையொப்பம்:

இடம் : பெயர்:

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறையைப் பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு **சகன வாதம்** என்னும் நோய்க்கான **""வாததிற்க்கு லேகியம்"** மற்றும் **"பஞ்சார்க்கத் தைலம்"** ஆகியவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி : கையொப்பம்:

இடம் : பெயர் :

சாட்சிக்காரர் கையொப்பம்:

பெயர் :

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FORM IV B WITHDRAWAL FORM

1. SL.NO : _____
2. OP / IP NO : _____
3. NAME : _____
4. RELIGION : H / C / M / O
5. AGE / GENDER : _____
6. OCCUPATION : _____
7. SOCIAL STATUS : _____
8. CONTACT NO : _____
9. DATE OF TRIAL COMMENCEMENT : _____
10. DATE OF WITHDRAWAL FROM TRIAL : _____
11. REASONS FOR WITHDRAWAL : _____

- Long absence at reporting : Yes / No
- Irregular treatment : Yes / No
- Shift of locality : Yes / No
- Increase in severity of symptoms : Yes / No
- Development of severe adverse drug reactions: Yes / No

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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BRANCH – III (SIRAPPU MARUTHUVAM)

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FORM IV C – DRUG COMPLIANCE FORM

Name of the Drug : VATHATHIRKU LEGHIYAM

Drugs issued : (Mg / Gram)

Drugs returned : (Mg / Gram)

S. NO	**DATE**	**DRUG TAKEN TIME**	
		MORNING / TIME	**EVENING / TIME**
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 13			
Day 14			
Day 15			
Day 16			
Day 17			
Day 18			
Day 19			
Day 25			
Day 26			

Day 27			
Day 28			
Day 29			
Day 30			
Day 31			
Day 37			
Day 38			
Day 39			
Day 40			
Day 41			
Day 42			
Day 43			
Day 44			
Day 45			
Day 46			
Day 47			
Day 48			

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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